DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94P–0036]

RIN 0910–AB66

Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations on nutrition labeling to require that the amount of *trans* fatty acids present in a food, including dietary supplements, be included in the amount and percent Daily Value (%DV) declared for saturated fatty acids. FDA is proposing that when *trans* fatty acids are present, the declaration of saturated fatty acids shall bear a symbol that refers to a footnote at the bottom of the nutrition label that states the number of grams of *trans* fatty acids present in a serving of the product. FDA also is proposing that, wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels, the amount of *trans* fatty acids be limited as well. In addition, the agency is proposing to define the nutrient content claim for "*trans* fat free." This proposal responds, in part, to a citizen petition on *trans* fatty acids in food labeling from the Center for Science in the Public Interest (CSPI). This action also is being taken to prevent misleading claims and to provide information to assist consumers in maintaining healthy dietary practices.

DATES: Written comments on the proposed rule should be submitted by (*insert date 90 days after date of publication in the* **Federal Register**). See section XI of this document for the proposed

effective date of a final rule based on this document. Written comments on the information collection requirements should be submitted by (*insert date 30 days after date of publication in the* **Federal Register**).

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Susan Thompson, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5587.

SUPPLEMENTARY INFORMATION:

I. Background

A. Nutrition Labeling

In the **Federal Register** of July 19, 1990 (55 FR 29847), FDA published a proposed rule entitled ''Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision'' (hereinafter referred to as ''the July 19, 1990, proposal'') to amend its food labeling regulations to require nutrition labeling on most food products that are meaningful sources of nutrients. Among other things, FDA proposed to revise the list of nutrients and food components that must be included in nutrition labeling by adding to that list saturated fatty acids, cholesterol, dietary fiber, and calories from fat.

During the comment period for the July 19, 1990 proposal, Congress passed, and the President signed into law, the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101–535). Section 403(q) (21 U.S.C. 343(q)) of the Federal Food, Drug, and Cosmetic Act

(the act), which was added by the 1990 amendments, specifies, in part, that certain nutrients and food components are to be included in nutrition labeling. Section 403(q)(2)(A) and (q)(2)(B) of the act state that the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) can, by regulation, add or delete nutrients to be included in the food label or labeling if he or she finds such action necessary to assist consumers in maintaining healthy dietary practices. In response to this provision, in the **Federal Register** of November 27, 1991 (56 FR 60366), FDA published a proposed rule entitled ''Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision'' (hereinafter referred to as ''the November 27, 1991, proposal'') to modify the July 19, 1990, proposal. In the November 27, 1991, proposal, the agency proposed to require that foods bear nutrition labeling listing certain nutrients and the amount of those nutrients in a serving of the food.

In the November 27, 1991 (56 FR 60366 at 60371) proposal, FDA also addressed the conditions under which other nutrients could voluntarily be included in nutrition labeling. FDA did not propose to include *trans* fatty acids (throughout this preamble FDA has used the terms ''*trans* fatty acids'' and ''*trans* fat'' interchangeably; likewise, for the terms ''saturated fatty acids'' and ''saturated fat'') among the nutrients that could voluntarily be listed on the nutrition label, but requested comments on this position.

In the **Federal Register** of January 6, 1993 (58 FR 2079), FDA issued a final rule entitled ''Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label'' (hereinafter referred to as ''the nutrition labeling final rule'') that prescribes how nutrition labeling is to be provided on the foods that are regulated by the agency. The new regulations required the declaration of total fat and of saturated fat, with the declaration of monounsaturated fat and polyunsaturated fat (both defined as the *cis* isomers only) required only when claims are made about fatty acids and cholesterol. Based on its review of the comments, the agency stated that it was premature to require the presence of *trans* fatty acids on the nutrition

label because of a lack of consensus on the dietary implications of *trans* fatty acids intake. However, the agency acknowledged that it might be necessary to revisit the labeling of *trans* fatty acids in the future (58 FR 2079 at 2090 to 2092).

B. Nutrient Content Claims

Section 403(r)(1)(A) of the act, which also was added by the 1990 amendments, provides that a product is misbranded if it bears a claim on its label or labeling that either expressly or implicitly characterizes the level of any nutrient of the type required to be declared as part of nutrition labeling, unless such claim has been specifically defined by regulation under section 403(r)(2)(A) of the act (or the product is otherwise exempted under the act). In response to this provision, FDA published two proposed rules in the **Federal Register** of November 27, 1991 (56 FR 60421 and 56 FR 60478). The first document entitled ''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms,'' covered general principles for nutrient content claims and proposed, in part, to define certain nutrient content claims, to provide for their use on food labels, and to establish procedures for the submission and review of petitions regarding the use of specific nutrient content claims. In the other document entitled ''Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food'' (hereinafter referred to as the ''fat, fatty acid, and cholesterol proposed rule''), the agency proposed definitions for fat, fatty acid, and cholesterol nutrient content claims, but not for ''saturated fat free.''

A number of comments in response to the fat, fatty acid, and cholesterol proposed rule strongly recommended that FDA define the term ''saturated fat free.'' In the **Federal Register** of January 6, 1993 (58 FR 2302 at 2419), FDA issued a final rule entitled ''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food,'' (hereinafter referred to as the ''nutrient content claims final rule'') (58 FR 2302 at 2419), that defined ''saturated fat free'' to mean that the food contains less than 0.5 gram (g) of saturated fat per reference amount customarily consumed

(''reference amount'') and that the level of *trans* fatty acids in the food does not exceed 1 percent of the total fat in the food (§ 101.62(c)(1)(i) (21 CFR 101.62(c)(1)(i))). FDA included the latter criterion because scientific evidence suggested that *trans* fatty acids act in a similar manner to saturated fat with respect to raising serum cholesterol and, therefore, should be present at insignificant levels when claims are made about saturated fats. The agency stated that it would be misleading for products that were labeled ''saturated fat free'' to contain measurable amounts of *trans* fatty acids because consumers would expect such products to be ''free'' of other components that significantly raise serum cholesterol. The agency stated that 1 percent was the appropriate threshold because analytical methods for measuring *trans* fatty acids below that level were not reliable (58 FR 2302 at 2332).

Technical comments that FDA received after publication of the nutrient content claims final rule objected to the 1 percent criterion for *trans* fatty acids in the definition of ''saturated fat free.'' A comment pointed out that a cookie containing 1.5 g of total fat would be allowed to have only 0.015 g of *trans* fatty acids, an amount that could not be accurately measured (58 FR 44020 at 44027). These comments persuaded FDA to revise the *trans* fatty acids criterion for the definition of ''saturated fat free'' in § 101.62(c)(1)(i) to require that a food contain less than 0.5 g *trans* fatty acids per reference amount and per labeled serving to be eligible to bear the claim. The agency selected this amount because of the reliable limit of detection of *trans* fatty acids and because it corresponds to the amount of saturated fat and total fat selected for the claims ''saturated fat free'' and ''fat free,'' respectively. FDA incorporated this change in technical amendments to the nutrient content claims final rule that it published in the **Federal Register** on August 18, 1993 (58 FR 44020 at 44032).

C. Disqualification/Disclosure Levels

The 1990 amendments addressed health claims by amending the act to specify, in part, that a food is misbranded if it bears a claim that expressly or by implication characterizes the relationship of any nutrient that is of the type required in section 403(q)(1) or (q)(2) of the act

to be in the label or labeling of the food to a disease or health-related condition unless the claim meets the requirements of a regulation authorizing its use. Section 403(r)(3)(A)(ii) of the act provides that a health claim may only be made for a food that does not contain, as determined by regulation, a nutrient in an amount that increases to persons in the general population the risk of a disease or health-related condition that is diet related. FDA describes these levels as ''disqualifying'' levels.

In the case of certain nutrient content claims, section 403(r)(2)(B) of the act, as amended, requires that the label or labeling of any food that contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related shall contain, prominently and in immediate proximity to such claim, the following statement: ''See nutrition information for _____ content.'' The blank shall identify the nutrient associated with the increased risk of disease or health-related condition. FDA refers to these levels as ''disclosure levels.''

FDA established disqualifying levels in § 101.14(a)(5) (21 CFR 101.14(a)(5)) for fat, saturated fat, cholesterol, and sodium in the health claims final rule (58 FR 2478, January 6, 1993). It also established disclosure levels for these nutrients in § 101.13(h) (21 CFR 101.13(h)) in the nutrient content claims final rule (58 FR 2302). The nutrient levels are the same for both disqualification and disclosure. During that rulemaking, the agency did not consider disqualifying or disclosure levels for *trans* fatty acids due to the inconclusiveness of scientific evidence concerning their impact on public health.

II. The Petition From the Center for Science in the Public Interest (CSPI)

CSPI submitted a citizen petition dated February 14, 1994, which was assigned FDA Docket No. 94P–0036/CP1. In the petition, CSPI stated that an increasing body of evidence suggests that dietary *trans* fatty acids raise blood cholesterol levels, thereby increasing the risk of coronary heart disease (CHD). The petitioner argued that the food labeling rules issued to implement the 1990 amendments do not adequately reflect the effect of dietary *trans* fatty acids on CHD. The petitioner

stated that consumers expect the number of grams of saturated fat listed on the nutrition label to represent all the ''heart-unhealthy'' fat in the product, and that, in many foods, the number of grams of saturated fat underestimates the total amount of ''heart-unhealthy'' fats because *trans* fatty acids are not included in the declared value. The petition included examples of products in which the declared amount of saturated fat accounted for only half of the ''heart-unhealthy'' fat. Accordingly, CSPI requested that FDA amend the definition of saturated fatty acids in § 101.9(c)(2)(i) (21 CFR 101.9(c)(2)(i)) to include *trans* fatty acids so that the declaration of saturated fat on the nutrition label would provide consumers with complete information on all ''heart-unhealthy'' fatty acids.

CSPI also requested that all saturated fat claims in § 101.62(c) be based on the combined level of saturated and *trans* fatty acids. The petitioner requested that these claims be prohibited unless the levels of saturated and *trans* fat combined meet FDA's saturated fat criteria for such claims. The petitioner contended that consumers may assume that the level of saturated fat allowed for these claims includes all of the ''heart-unhealthy'' fat in a product. The petitioner stated that the level allowed should include *trans* fatty acids because of the substantial and growing amount of evidence demonstrating that *trans* fatty acids increase the risk of CHD.

Further, the petitioner maintained that without a limit on the *trans* fatty acid content in foods with the previously mentioned claims, manufacturers could replace saturated fat with *trans* fatty acids. To support its position, the petitioner provided numerous product labels bearing nutrient content claims for the content of saturated fat or cholesterol. These products appear to contain *trans* fatty acids (calculated by subtracting the sum of saturated, polyunsaturated, and monounsaturated fat from total fat) in higher amounts than saturated fatty acids.

The petitioner stated that FDA has already taken a positive step in this area by imposing a 0.5 g limit on *trans* fat allowed in foods that have the claim ''saturated fat free.'' However, the petitioner requested that the criteria for saturated fat of 0.5 g should refer to the level of saturated and *trans* fat combined. The petitioner pointed out that without this change, the level

of ''heart-unhealthy'' fat can be almost 1.0 g, which is the limit for ''low'' in saturates. The petitioner stated that consumers expect foods that have the claim ''saturated fat free'' to be free of components that significantly raise serum cholesterol. Thus, it would be misleading for such products to contain significant amounts of ''heart-unhealthy'' fat.

With respect to ''low in saturated fat,'' this claim is currently defined in § 101.62(c)(2)(i) as 1 g or less of saturated fat per reference amount and 15 percent or less of calories from saturated fat. The petitioner requested that this definition should read ''1 g or less total of saturated fatty acids and *trans* fatty acids combined per reference amount customarily consumed and not more than 15 percent of calories from saturated fatty acids and *trans* fatty acids combined.''

Similarly, the petitioner requested that the definition for ''reduced saturated fat'' in § 101.62(c)(4)(i) of at least a 25 percent reduction in saturated fat should be amended to be a 25 percent reduction in saturated and *trans* fat combined.

The petitioner also requested that all saturated fat claims for meal products and main dishes (i.e., ''saturated fat free'' in § 101.62(c)(1)(i), ''low in saturated fat'' in § 101.62(c)(3)(i), and ''reduced saturated fat'' in § 101.62(c)(5)(i)) be amended to reflect the combined level of saturated and *trans* fatty acids. The petitioner made a similar request regarding ''lean'' and ''extra lean'' claims (§ 101.62(e)).

In addition, the petitioner requested that the saturated fat threshold on all cholesterol claims for foods, meal products, and main dishes (i.e., ''cholesterol free'' (§ 101.62(d)(1)(i)(C) and (d)(1)(ii)(C)), ''low cholesterol'' (§ 101.62(d)(2)(i)(B), (d)(2)(ii)(B), (d)(2)(iii)(B), (d)(2)(iv)(B), and (d)(3)), and ''reduced cholesterol'' (§ 101.62(d)(4)(i)(B), (d)(4)(ii)(B), (d)(5)(i)(B), and (d)(5)(ii)(B))) be amended to reflect the combined level of saturated and *trans* fatty acids.

CSPI also requested that the disqualification and disclosure levels for health and nutrient content claims be amended to reflect combined levels of saturated fat and *trans* fatty acids. For example, CSPI requested that the disqualifying nutrient level for health claims in § 101.14(a)(5)

and the disclosure level for nutrient content claims in § 101.13(h)(1) be changed from 4 g saturated fat to 4 g of saturated and *trans* fatty acids combined.

Further, CSPI requested that FDA limit ''vegetable oil'' claims (e.g., ''made with vegetable oil,'' ''cooked in 100 percent vegetable oil'') to foods that are low in both saturated and *trans* fatty acids. Finally, the petitioner requested that FDA require that ''partially hydrogenated'' fat be listed on food labels as ''partially saturated'' fat.

On July 13, 1998, CSPI amended its petition in a way that would maintain the definition of saturated fat in § 101.9(c)(2)(i), yet provide consumers with information on the *trans* fatty acid content of the food. The amended petition continued to request that the number of grams of *trans* fatty acids in a food be added to the number declared for saturated fatty acids. However, in its amendment, the petitioner suggested two methods that would alert the consumer to the presence of *trans* fatty acids. In the first method, an asterisk would be used after ''Saturated fat'' when *trans* fatty acids are present. The asterisk would refer to an asterisk at the bottom of the nutrition label followed by a footnote explaining that the declaration of saturated fatty acids ''Contains _____ g of*trans* fat.'' Alternatively, CSPI suggested that the terminology on the nutrition label be changed from ''Saturated fat'' to ''Saturated + *trans* fat.''

The agency's tentative response to the petition and to the comments on the petition follows.

III. Statutory Authority

FDA is proposing to amend its regulations governing nutrient content claims and nutrition labeling to include provisions on *trans* fatty acids. FDA is proposing to take these actions under sections 201(n) 403(a)(1), 403(q), 403(r), and 701(a) of the act (21 U.S.C. 321(n), 343(a)(1), 343(q), 343(r), and 371(a)). Under section 201(n) of the act, labeling is misleading if it fails to reveal facts that are material in the light of representations made in the labeling or that are material with respect to the consequences that may result from the use of the food under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual. Section 403(a)(1) of the act prohibits labeling that is false or misleading. Section 403(q) of the act allows

the Secretary, in section 403(q)(2)(A) of the act, to require by regulation nutrition information about nutrients other than those specified in section 403(q)(1) of the act to assist consumers in maintaining healthy dietary practices. Under section 403(r) of the act, a food is misbranded if its labeling uses terms that have not been defined by regulation issued under section 403(r)(2)(A)(i) to characterize the level of any nutrient in a food, or if, in violation of section 403(r)(2)(A)(iv), cholesterol levels are not specified in immediate proximity to saturated fat claims. In addition, under section 403(r)(2)(A)(vi) of the act, the Secretary by regulation may prohibit a claim about the level of a nutrient because it is misleading in light of the level of another nutrient in the food. Section 403(r)(2)(B) of the act requires that the labeling of any food bearing a nutrient content claim that contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related must contain, prominently and in immediate proximity to such nutrient content claim, a disclosure statement specified by that section of the act. Moreover, section 403(r)(3)(A)(ii) of the act provides that FDA establish by regulation disqualifying levels for health claims to ensure that health claims cannot be made for products that contain nutrients in amounts that increase to persons in the general population the risk of a disease or health-related condition that is diet related. Finally, section 701(a) of the act gives the Secretary the authority to issue regulations for the efficient enforcement of the act.

IV. *Trans* Fatty Acids

A. Definitions

1. Fats

Fats are energy-yielding nutrients that are found in most foods. Dietary fats are composed of fatty acids and glycerol. Dietary fatty acids consist of carbon chains of various lengths and a terminal carboxyl group. The carbon atoms in these chains are connected by single or double bonds. Hydrogen atoms are attached to the noncarboxyl carbons.

2. Fatty Acid Nomenclature

A saturated fatty acid has no double bonds between the carbon atoms in the chain. Therefore, a maximum number of hydrogens (i.e., 2) are attached to each carbon atom, except for the end carbons, and ''saturate'' the carbon chain. An ''unsaturated'' fatty acid may contain one or more double bonds between carbon atoms and, therefore, two fewer hydrogen atoms per double bond. A fatty acid with a single double bond is called a ''monounsaturated fatty acid.'' A fatty acid with two or more double bonds is called a ''polyunsaturated fatty acid.''

Fatty acids are identified by the number of carbons and the number of the carbon-carbon double bonds. For example, stearic acid, a saturated fatty acid, has 18 carbons and no double bonds. The shorthand notation for this fatty acid is ''C18:0.'' Some examples of other saturated fatty acids are lauric (C12:0), myristic (C14:0), and palmitic (C16:0) acids. The most common dietary monounsaturated fatty acid is oleic acid, C18:1, which has 18 carbons and one double bond. The most common dietary polyunsaturated fatty acid is linoleic acid, C18:2, which has 18 carbons and 2 double bonds.

3. *Cis* and *Trans* Isomers

Most naturally-occurring dietary unsaturated fatty acids are in a ''*cis*'' configuration, i.e., the two hydrogen bonds attached to two carbons are on the same side of the molecule at the double bond which gives the molecule a ''bend'' at the site of the double bond. These bent molecules cannot pack easily together, so fats of these molecules are more often in a liquid form. In a ''*trans*'' configuration, the hydrogen atoms attached to the carbon atoms at a double bond are not on the same side of the double bond (''*trans*'' means ''across'' in Latin). This arrangement of hydrogen atoms stabilizes the molecule in a relatively straight contour. *Trans* isomers are primarily the result of the hydrogenation process. One common *trans* fatty acid is monounsaturated *trans*-C18:1.

4. Hydrogenation

Chemical hydrogenation is the process by which hydrogen atoms are added to unsaturated sites on the carbon chains of fatty acids in the presence of catalysts, thereby reducing the number of double bonds. ''Partial hydrogenation'' describes an incomplete saturation of the double bonds, in which some double bonds remain but may be moved in their positions on the carbon chain and changed from a *cis* to *trans* configuration or isomer.

Hydrogenation increases the melting point, shelf life, and flavor stability of unsaturated fatty acids. Through hydrogenation, oils (i.e., fats in liquid form), such as soybean, safflower, and cottonseed oil, which are rich in unsaturated fatty acids, are converted to semi-solids and solids that are useful in margarines and vegetable shortenings.

Hydrogenation also occurs in the digestive tract of ruminant animals and results in some *trans* isomers in the fat components of dairy and meat products from these animals. These isomers usually make up only a small percent of the total fatty acids of such products.

The partial hydrogenation process was developed in the 1930's and has been in widespread commercial use since the 1940's. Dietary fats containing hydrogenated fatty acids, such as those used in margarine, have gradually displaced animal fats, such as butter and lard (Refs. 1 and 2). About two-thirds of the dietary fat consumed in the 1940's was of animal origin. The balance was reversed by the 1960's, with two-thirds coming from fats of vegetable origin. This trend resulted in a decrease in the intake of saturated fat and an increase in the intake of polyunsaturated and *trans* fatty acids (Ref. 1).

B. Review of the Science

In support of its petition, CSPI cited a number of scientific publications that related consumption of *trans* fatty acids to increased risk of CHD, as well as statements by government and professional bodies about *trans* fatty acids. FDA has reviewed both the scientific evidence cited in the petition and available human study evidence published since receipt of the petition. There are two recent reviews of findings from animal studies on the effects of feeding animals

trans fatty acids (Refs. 1 and 3). These reviews indicate that results from animal feeding studies do not parallel findings from human intervention and epidemiological studies. Although the results from the animal and human studies differ, FDA considers the findings from human studies more directly relevant and, as explained below, persuasive evidence with which to evaluate the influence of *trans* fatty acid consumption on CHD in humans.

1. Reviews by the Federal Government and the National Academy of Sciences (NAS)

A review of reports published by the Federal Government and the NAS between the late 1980's and the present time on dietary *trans* fatty acids shows that conclusions and recommendations are evolving as results from significant new studies become available. For example, a report by the Surgeon General in 1988 (Ref. 2) concluded that *trans* fatty acids appeared to be neutral in their effects on serum lipids predictive of CHD risk. Based on a limited number of animal and observational studies, the Food and Nutrition Board of the NAS concluded in 1989 that *trans* fatty acids appeared to have no deleterious health effects (Ref. 4).

More recently, the 1993 publication from the National Cholesterol Education Program (NCEP) entitled "Second Report of the Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults" (Ref. 5) stated:

Recent research indicates that *trans* fatty acids raise LDL-cholesterol levels nearly as much as do cholesterol-raising saturated fatty acids. *Trans* fatty acids account for about 3 percent of total calories in the American diet; this amount causes a definite increase in LDL-cholesterol levels, but of course less than the more abundant cholesterol-raising saturated fatty acids. Improvements in food technology in the future may reduce the *trans* fatty acid content of the American diet. In the meantime patients with high cholesterol should limit their intake of foods high in *trans* fatty acids such as hydrogenated shortenings, some margarines and foods containing these fats.

The fourth edition of Dietary Guidelines for Americans (Ref. 6), a joint 1995 publication from the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS), stated:

Partially hydrogenated vegetable oils, such as those used in many margarines and shortenings, contain a particular form of unsaturated fat known as *trans*-fatty acids that may raise blood cholesterol levels, although not as much as saturated fat.

2. Published Human Research Studies

FDA previously reviewed studies on *trans* fatty acids in the **Federal Register** of November 27, 1991 (56 FR 60366 at 60371) proposal on nutrition labeling and in its 1993 final rule for a health claim for dietary saturated fat and cholesterol and CHD (58 FR 2739 at 2744). The latter document included a review of studies considered in that health claim evaluation. As a result of its review, the agency concluded that the available scientific evidence was insufficient to make a policy decision regarding dietary *trans* fatty acids and risk of CHD, noting that the ''low fat'' eligibility requirement gave little room for products to contain high levels of *trans* fatty acids. The agency has focused its current review on studies cited in the petitioner's submission plus recent studies in humans identified by a supplemental literature search.

To target its review of the available evidence on *trans* fatty acids and CHD risk, the agency focused on the physiological measures that were identified as valid predictors of increased risk for CHD, which were published in the *Second Report of the Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults* (Ref. 5). That Expert Panel identified a high blood cholesterol level in adults as a major risk factor for CHD. In particular, that study reported that a direct relationship had been demonstrated between serum low-density lipoprotein cholesterol (LDL–C) concentrations and rate of CHD. Intervention studies had shown that lowering plasma LDL–C by dietary means and drug therapy can reduce this risk, and recommendations for dietary interventions were made relative to their effect on serum LDL–C concentrations.

Based on the findings of the NCEP Expert Panel (Ref. 5), FDA has concluded that an examination of the effects of *trans* fatty acids on serum LDL–C would provide the strongest evidence, and should be the primary criterion, to evaluate whether *trans* fatty acids influence the risk of CHD. The agency also compiled changes in serum total and high density lipoprotein

cholesterol (HDL–C) and serum lipoproteins to present a more complete picture of serum lipid changes.

FDA reviewed findings from intervention and observational studies to evaluate the evidence that dietary *trans* fatty acids influence blood lipid levels in humans and increase their risk of CHD. In the present review, FDA gave greater weight to results from dietary intervention studies because of the ability of intervention studies to provide evidence for a cause-effect relationship (Ref. 4). FDA regarded results from observational (epidemiologic) studies, which can identify associations between dietary intake and risk of CHD but which do not provide direct evidence for cause and effect (Ref. 4), as indirect evidence for a relationship between *trans* fatty acids intake and risk of CHD. Because ''repeated and consistent findings of an association between certain dietary factors and diseases are likely to be real and indicative of a cause-effect relationship'' (Ref. 4), FDA heavily weighted the consistency of results among studies.

Results of the intervention and observational studies are shown in Tables 1 and 2 of Appendix A of this document, respectively. A summary of the effects of *trans* fatty acids on serum LDL–C, shown in the dietary intervention studies detailed in Table 1 of Appendix A is presented in Table 3 of Appendix A.

a. *Intervention studies*. Controlled dietary intervention studies (feeding trials) using test fats containing *trans* fatty acids have been conducted in the Netherlands (Refs. 7 and 8), Norway (Ref. 9), Finland (Ref. 10), Australia (Refs. 11 and 36), and the United States (Refs. 12, 13, 14, 15, 34, and 82). As detailed in Table 1 of this document, test products consisted of partially hydrogenated vegetable and fish oils commercially available in the study country or products especially prepared for the study and similar to the partially hydrogenated oil products used in the country.

Serum LDL–C levels measured after consumption of diets containing low levels of *trans* fatty acids were compared with serum LDL–C levels measured after consumption of diets in which *trans* fatty acids replaced *cis*-polyunsaturated fatty acids (PUFA's) (mainly linoleic acid), *cis*-

monounsaturated fatty acids (MUFA's) (mainly oleic acid), or saturated fatty acids (varying combinations of lauric, myristic, palmitic, and stearic acids). Within studies, the saturated fatty acid content of diets was not increased, and in some studies was decreased, by the inclusion of *trans* fat sources. See Table 1 of this document for details about fatty acids composition of diets.

In these studies, partially hydrogenated oils were incorporated into diets fed to adult men and women for experimental periods of 3-week (Refs. 7, 8, 9, 11, and 36), 4.5-week (Ref. 13), 5-week (Refs. 10, 34, and 82), or 6-week (Refs. 12, 14, and 15) intervals at levels providing 2.4 to 10.9 percent of energy intake as *trans* fatty acids. At the levels of dietary energy consumed, study participants consumed from 2.1 g/day to 38.3 g/day of *trans* fatty acids (see Table 1 of Appendix A of this document for details).

Overall, consumption of diets containing higher levels of *trans* fatty acids resulted in significantly higher LDL–C levels when *trans* fatty acids sources replaced fats high in *cis*-PUFA (mainly linoleic acid) or *cis*-MUFA (mainly oleic acid). With respect to studies comparing diets containing *trans* fatty acids to diets containing higher levels of *cis*-PUFA, Lichtenstein et al. (1993) found that LDL–C levels were 8.4 percent higher in 14 mildly hypercholesterolemic subjects after consumption of NCEP Step 2 diets containing 12.5 g/day of *trans* fatty acids for 3 weeks compared to a linoleic acid diet providing a daily intake of only 1.2 g/day of *trans* fatty acids (Ref. 13). (The Step 2 diet is an intensive dietary therapy for high blood cholesterol recommended by the NCEP when less restrictive dietary intervention has not resulted in serum LDL–C reduction (Ref. 5).) In a second study, Lichtenstein et al., (1999) (Ref. 82) found that serum LDL–C concentrations increased in a stepwise manner when 36 subjects consumed NCEP Step 2 diets containing four hydrogenated soybean oil products (semiliquid margarine, soft margarine, shortening, and stick margarine) compared to a Step 2 diet containing unhydrogenated soybean oil. *Trans* fatty acids intakes of subjects consuming hydrogenated products ranged from 2.9 g/day for men and 2.1g/ day for women consuming the semiliquid margarine diet to 20.8 g/day for men and 15.8 g/day

for women consuming the stick margarine diet. *Trans* fatty acids intakes of subjects consuming the soybean oil diet were 1.7 g/day for men and 1.3 g/day for women (Ref. 82).

Zock and Katan (1992) also reported LDL–C levels 8.5 percent higher in 56 normolipidemic subjects after consumption of a diet containing 24.5 g/day of *trans* fatty acids compared to a linoleic acid diet providing less than 0.05 g/day of *trans* fatty acids (Ref. 8). In a less rigorously controlled study, Wood et al. (Ref. 15) reported that serum LDL–C levels were increased 6.1 percent in 38 healthy men after consumption of a hard margarine diet containing at least 15.8 g/day of *trans* fatty acids compared to a soft margarine diet with unspecified, but presumably lower, levels of *trans* fatty acids (Ref. 14).

Other studies compared *trans* diets to diets containing oleic acid. Compared to an oleic acid diet providing about 2 g/day *trans* fatty acids, LDL–C levels in 58 healthy men and women were 6.0 percent higher after consumption of diets containing moderate levels of *trans* fatty acids (7.6 g/day in an 1,800 kilocalories (kcal)/day diet or 11.8 g/day in a 2,800 kcal/day diet) and 7.8 percent higher after consumption of diets containing higher levels of *trans* fatty acids (13.2 g/day for the 1,800 kcal diet or 20.5 g/day for the 2,800 kcal diet) (Ref. 12). Mensink and Katan (1990) had earlier reported 13.9 percent higher levels of LDL–C in 59 healthy men and women after consumption of a diet containing 33.6 g/day of *trans* fatty acids compared to an oleic acid diet providing no *trans* fatty acids (Ref. 7). Nestel et al. (1992) also reported LDL–C levels 9.2 percent higher in 27 mildly hypercholesterolemic men after consumption of a diet providing 15.6 g/day of *trans* fatty acids compared to an oleic acid diet providing intakes of 3.8 g/day *trans* fatty acids (Ref. 11). It should be noted that changes in serum total cholesterol concentrations tended to parallel changes in LDL–C in these studies; HDL–C levels either did not differ significantly between treatment groups or were lower after consumption of *trans* fatty acid diets than after *cis*-MUFA or PUFA diets (see Table 1 of Appendix A of this document).

Consumption of diets in which *trans* fatty acids replaced some dietary saturated fatty acids resulted in LDL–C levels that were not significantly different or were lower than LDL–C levels

after consumption of diets containing saturated fatty acids, although generally not as low as the reduction in saturated fatty acids would suggest. Aro et al. (Ref. 10), Zock and Katan (Ref. 8), and Nestel et al. (Ref. 11) reported that LDL–C levels following consumption of diets containing 24.9, 24.5, or 15.6 g/day, respectively, of *trans* fatty acids were not significantly different from LDL–C levels following consumption of saturated fatty acid diets providing mainly stearic acid or palmitic acid and providing 1 to 3 g/day of *trans* fatty acids. Judd et al. (1994) reported no significant difference in LDL–C in 58 apparently healthy subjects after consumption of a diet containing a high level of *trans* fatty acids (13.2 or 20.5 g/day) compared to a saturated fatty acid diet providing about 2 g/day of *trans* fatty acids (Ref. 12). Although, at a moderate level of *trans* fatty acid intake (7.6 or 11.8 g/day), LDL–C levels were 2.7 percent lower compared to the saturated fatty acid diet, these LDL–C levels were still significantly higher than after consumption of the *cis*-MUFA (oleic acid) diet (Ref. 12). In these diets, *trans* fatty acids replaced lauric, myristic, and palmitic acids; stearic acid levels provided 3 percent of energy in all diets.

In a 1998 study, Judd et al. (Ref. 34) reported that LDL–C decreased 4.9 percent after consumption of a diet containing a *trans* fatty acids margarine and providing 13 and 9 g/day of *trans* fatty acids to men and women, respectively, compared to a diet containing butter and foods providing 9 and 7 g/day of *trans* fatty acids for men and women (Ref. 34). At *trans* fatty acids intakes of 6.4 g/day or 6.8 g/day (Ref. 36) and 12.5 g/day (Ref. 13), LDL–C levels were lower in mildly hypercholesterolemic subjects after replacement of some saturated fatty acids by *trans* fatty acids. Almendingen et al. (Ref. 9) also reported 6.0 percent lower LDL–C levels in 30 healthy men after consumption of diets containing 22.6 to 38.3 g/day of *trans* fatty acids from partially hydrogenated soy oil than after a saturated fat (butter) diet providing only 2 to 4 g/day of *trans* fatty acids but no difference after consumption of a diet containing 21.6 to 36.1 g/day of *trans* fatty acids from partially hydrogenated fish oil compared to the saturated fat diet. Mensink and Katan (Ref. 7) reported LDL–C levels 3.2 percent lower in 59 healthy men and women after

consumption of a diet containing 33.6 g/day of *trans* fatty acids than after a saturated fatty acid diet high in lauric and palmitic acids and containing 2.4 g/day *trans* fatty acids.

In a 1999 study, Lichtenstein et al. (Ref. 82), found that serum LDL–C concentrations decreased in a stepwise manner when 36 subjects consumed NCEP Step 2 diets containing four hydrogenated soybean oil products (stick margarine, shortening, soft margarine, and semiliquid margarine) compared to a butter diet containing the same amount of total fat and 3.9 g/day and 2.9 g/day of *trans* fatty acids for men and women, respectively. *Trans* fatty acids intakes of men and women consuming stick margarine were 20.8 and 15.8 g/day, shortening 9.7 and 12.9 g/day, soft margarine 10.2 and 7.8 g/day, and semiliquid margarine 1.7 and 1.3 g/day (Ref. 82).

Results from Mensink and Katan (Ref. 7), Judd et al. (1994 and 1998) (Refs. 12 and 34), and Lichtenstein et al. (1993 and 1999) (Refs. 13 and 82) indicate that consumption of diets containing *trans* fatty acids results in LDL–C levels between those observed after consumption of saturated fatty acid diets and *cis*-MUFA and PUFA diets; i.e., lower than after consumption of saturated fatty acid diets but higher than after *cis*-MUFA or PUFA diets. As noted previously in comparisons with *cis*-MUFA and PUFA diets, changes in total cholesterol concentrations also tended to parallel changes in LDL–C levels after consumption of *trans* fatty acid diets compared to saturated fatty acid diets; HDL–C levels either did not differ significantly between treatment groups or were lower after consumption of *trans* fatty acid diets than after saturated fatty acid diets.

Interpretation of these intervention studies described previously is complicated because *trans* fatty acids replace other dietary fatty acids that also affect serum cholesterol levels. However, comparing fatty acid composition of the test and control diets, these studies consistently indicate that consumption of diets containing fats with higher levels of *trans* fatty acids results in increased serum LDL–C, the major dietary risk factor for CHD, compared with diets containing *cis*-MUFA or PUFA fat sources and lower levels of *trans* fatty acids. The studies that compare a saturated fat diet with a diet in which some of the saturated fat has been replaced with *trans* fat also indicate

that *trans* fatty acids, like saturated fatty acids, increase serum LDL–C. However, these studies do not conclusively show whether, on a gram-for-gram basis, the rise in LDL–C from *trans* fatty acids is as great as the rise that results from saturated fatty acids.

b. *Observational (epidemiologic) studies.* The observational studies included in FDA's review in this proposed rule used two approximations of *trans* fatty acids intake (adipose tissue concentrations and dietary data) to examine associations between *trans* fatty acids intake and CHD risk. Details of the observational studies are provided in Table 2 of Appendix A of this document.

One case-control study of 1,388 men in 9 countries (the ''EURAMIC Study'') found no association between *trans* fatty acid concentrations in adipose tissue and the risk of acute myocardial infarction (MI) (Ref. 16). A second case-control study of 250 men in the United Kingdom found that the mean concentration of *trans* fatty acids in adipose tissue was lower in cases of sudden cardiac death (2.68 percent of total fatty acids) than in healthy controls (2.86 percent of total fatty acids) and that multivariate odds ratios for *trans* fatty acids were not independently related to the risk of sudden cardiac death (Ref. 17). Although *trans* fatty acid concentrations in adipose tissue have been reported to reflect dietary intake, for example, London et al. (Ref. 37), the relationship of differences in adipose tissue concentrations of fatty acids to CHD risk remains uncertain.

Other observational studies have reported positive associations between estimated dietary intakes of *trans* fatty acids and incidence of CHD manifested as risk of MI or acute MI (Refs. 16 and 18), risk of nonfatal MI (Refs. 19, 38, 20, and 21), risk of mortality from CHD (Refs. 17, 19, 20, 21, and 22), or increased risk of CHD predicted by higher levels of serum total cholesterol and LDL–C (Refs. 18, 22, 23, and 38). In a Massachusetts case-control study of the risk of MI in 239 men and women diagnosed with a first MI and in an age- and sex-matched control group (n=282), relative risk of MI was 2.03 in the highest quintile of *trans* fatty acids intake (about 6.7 g/day) compared to the lowest quintile of intake (about 3.0 g/day) (Ref. 18).

These estimates took into account adjustments for standard risk factors for CHD as well as intakes of saturated fat, monounsaturated fat, linoleic acid, and cholesterol.

Trans fatty acids intake showed a statistical association with serum LDL–C (r = 0.09) in a multiple linear regression analysis in 748 men in the Normative Aging Study, conducted between 1987 and 1990 (Ref. 23). The mean *trans* fatty acids intake was determined to be 1.6 percent of energy intake and did not differ between groups who did or did not have high serum total cholesterol concentrations 3 to 5 years earlier. Associations between *trans* fatty acids intake and serum LDL–C were stronger in the group who previously had high serum total cholesterol concentrations.

In an univariate intercohort analysis of 16 cohorts of men in the Seven Countries Study, Kromhout et al. (Ref. 22) reported that mean intakes of *trans* fatty acids of cohorts ranging from 0.05 percent to 1.84 percent of energy were associated with serum total cholesterol (r = 0.70) and with 25-year mortality rates from CHD (r = 0.78). In this study, estimated intakes of *trans* fatty acids were based on composites of foods retrospectively collected and analyzed in 1987 to approximate average food intakes of each cohort reported during the baseline period 1958–1964. Independent effects of individual fatty acids and dietary cholesterol on serum total cholesterol and CHD mortality could not be analyzed in multivariate models because mean intakes of individual saturated fatty acids, *trans* fatty acids, and dietary cholesterol were highly correlated among the cohorts.

One prospective cohort study in Finland (Ref. 20) and three in the United States (Refs. 19, 21, and 38) have reported higher CHD risk in population quintiles with the highest intakes of *trans* fatty acids compared to the quintiles with the lowest *trans* fatty acid intakes. In 21,930 male smokers, who were participants in the Finnish Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study, higher *trans* fatty acid intakes were associated with higher risk of major coronary event and risk of CHD death. Relative risk (RR) of a major coronary event was 1.19 in the highest intake quintile (median intake 5.6 g/day) compared to the lowest quintile (median intake 1.3 g/

day) when the estimate was adjusted for age and supplement group. An RR of an event associated with *trans* fatty acid ingestion that is greater than 1 would be a risk that is more likely to be associated with ingestion of *trans* fatty acids. Additional adjustment for cardiovascular risk factors reduced the RR to 1.14. With adjustments for age and supplement group, the RR of CHD death was 1.38 in the highest intake quintile compared to the lowest quintile. The association was also significant (RR = 1.39) after adjustment for cardiovascular risk factors and dietary fiber. The multivariate RR of coronary death for intakes of *trans* isomers from hydrogenated vegetable fats was 1.23 (Ref. 20).

In a cohort of 43,757 male health professionals followed for 6 years, median intakes of *trans* fatty acids were 1.5 g/day and 4.3 g/day for the lowest and highest quintiles. Between these intake quintiles, the RR of total MI (chi square for trend) was 1.27 after adjustment for age, cardiovascular risk factors, and dietary fiber intake. The RR of fatal CHD was similar to that for total MI (Ref. 19). In a cohort of 69,181 female nurses who reported that they had not changed their margarine consumption over a 10-year period, the RR of CHD (nonfatal MI or death from CHD) in relation to energy-adjusted *trans* fatty acids intake was 1.67 for the highest intake quintile (mean intake 5.7 g/day) compared to the lowest intake quintile (mean intake 2.4 g/day) after 8 years of followup (Ref. 21). Because intake of *trans* fatty acids was strongly associated with intake of MUFA and linoleic acid, the RR value reported here includes adjustments for dietary lipids. After 14 years of followup in this study, the RR of CHD in relation to energy-adjusted *trans* fat intake was 1.53 (Ref. 38).

These epidemiologic investigations of associations between dietary *trans* fatty acids and risk of CHD must be interpreted with caution because of the imprecision associated with the dietary collection methodologies used, the difficulty of eliminating confounding factors, and because no dose-response relationship has been demonstrated in the epidemiologic studies. However, despite these generally recognized deficiencies in the observational studies, the repeated and consistent

findings from the observational studies suggest that consumption of *trans* fatty acids is associated with adverse effects on CHD risk in humans, which supports the findings from intervention studies.

c. *Estimates of dietary intake of trans* fatty acids in the U.S. population. Estimates of mean consumption of dietary *trans* fatty acids in the United States range from about 3 g/day to about 13 g/day. Values have been estimated from national food disappearance data (Refs. 24, 25, and 39), from dietary intakes reported in a national food consumption survey (Ref. 26), and from food frequency data collected in observational studies of *trans* fatty acids intakes and risk of CHD (Refs. 18, 19, 21, and 23).

Based on national food disappearance data, estimated mean values for the daily per capita consumption of total *trans* fatty acids were variable: 12.8 g/day (Ref. 24), 10.2 g/day (Ref. 39), and 8.1 g/day (Ref. 25). Values estimated from food disappearance data tend to be high because the data are collected before subtraction of losses that occur during processing, marketing, cooking, and plate waste. However, each of these three estimates did apply corrections for these types of losses to varying degrees.

One estimate of mean intake of *trans* fatty acids in the U.S. population has been made based on dietary intake data reported by a nationally representative sample of individuals in the 1989 through 1991 Continuing Survey of Food Intakes of Individuals (CSFII) (Ref. 26). For this estimate, a food composition database with more extensive data on the *trans* fatty acids contents of foods than those used for many previous estimates was developed incorporating data released by USDA in 1995. The estimated mean intake of *trans* fatty acids derived by this approach was 5.3 g/day (2.6 percent of calories) and the 90th percentile intake was 9.4 g/day for individuals 3 years of age and older in the U.S. population. In comparison, the total saturated fatty acid intake was 25.0 g/day and the 90th percentile intake was 40.6 g/day for this population.

The previous estimates are somewhat higher than estimates made from observational studies of *trans* fatty acids intake and risk of CHD in the United States (Ref. 18, 19, 21, and 23). Estimates of mean *trans* fatty acids intake based on food frequency data were 4.4 g/day for men and 3.6

g/day for women in one observational study in the United States (Ref. 18) and 3.4 g/day for men in another (Ref. 23). These estimates included groups of participants who had MI or previous detection of elevated serum cholesterol levels and subjects without those characteristics. Some studies presented mean or median intakes for quintiles of the population studied. Median intakes were 3.1 g/day for men and 3.0 g/day for women in the lowest intake quintile and 6.7 g/day for men and 6.8 g/day for women in the highest quintile (Ref. 18). Another study reported intakes of 1.5 g/day and 5.3 g/day, respectively, for the lowest and highest quintiles of male health professionals (Ref. 19). For female nurses in the United States, mean energy-adjusted intakes of *trans* fatty acids were 2.4 and 5.7 g/day, respectively, for the lowest and highest quintiles of *trans* fatty acids intake (Ref. 21). Because data on *trans* fatty acids contents of food in food composition data bases were considered less than adequate for most foods except fats and oils at the times these estimates were made (Ref. 28) and because some commonly consumed foods such as cookies, crackers, and some salad dressings contain substantial amounts of *trans* fatty acids (Refs. 29 and 30), the food composition data component of these estimates may not have included *trans* fatty acids content of all foods consumed. In addition, these estimates, as well as all estimates of intakes based on food frequency data (Ref. 27), may be subject to systematic bias toward either over- or underestimation of quantities consumed, depending on the design of the food frequency questionnaire.

Overall, these estimates of mean *trans* fatty acids intakes are similar to amounts of *trans* fatty acids provided in intervention studies in the United States in which *trans* fatty acids contents were determined by chemical analysis of duplicate portions of the diets and in which statistically significant increases in serum LDL–C were reported compared to diets containing *cis*-PUFA (Refs. 13, 34, and 82) or *cis*-MUFA (Ref. 12). The intakes of *trans* fatty acids in these intervention studies were 9 and 13 g/day (Ref. 34), 9.7 and 12.9 g/day (Ref. 82), 12.5 g/day (Ref. 13), and as low as 7.6 g/day (Ref. 12). Levels in these intervention studies are very similar to the estimated intakes of the many individuals in the United States whose *trans* fatty acids consumption is in

the upper half of the intake distribution (i.e., greater than the mean of 5.3 g/day) derived from food consumption reported by a nationally representative sample of individuals.

d. *Summary.* Controlled intervention (feeding) studies in different population groups in the United States and other countries consistently indicate that consumption of diets containing *trans* fatty acids results in elevations of serum LDL–C (the major dietary risk factor for CHD) compared with consumption of diets containing *cis*-monounsaturated or polyunsaturated fat sources. Although these studies are too short in duration to provide direct evidence on the incidence of CHD, they provide evidence for an effect of dietary *trans* fatty acids on LDL–C, a biomarker and major risk factor for CHD. In addition, positive statistical associations are consistently reported in observational studies between estimated dietary intake of *trans* fatty acids in free-living populations and incidence of CHD manifested as first acute MI, mortality from CHD, or increased risk of CHD predicted by higher levels of serum total cholesterol and LDL–C.

The available studies do not provide a definitive answer to the question of whether *trans* fatty acids have an effect on LDL–C and CHD risk equivalent to saturated fats on a gram-for-gram basis. They also do not provide information about mechanisms responsible for the observed increases in LDL–C. However, the repeated and consistent findings under a variety of conditions that consumption of *trans* fatty acids (1) results in increases in serum LDL–C when dietary saturated fatty acids are not increased in intervention studies, and (2) is associated in observational studies with increased risk of CHD are strong evidence of a relationship between consumption of higher levels of *trans* fatty acids and increased risk of CHD.

Estimates of mean dietary intake of *trans* fatty acids by the U.S. population are similar to the levels of *trans* fatty acids consumed in three intervention trials in the United States in which serum LDL–C was adversely affected and in which dietary content of *trans* fatty acids was determined by chemical analysis (9 and 13 g/day, 12.5 g/day, and as low as 7.6 g/day) (Refs. 34, 12, and 13). In addition, statistically significant associations between *trans* fatty acids intakes

and increases in serum LDL–C concentrations among free-living populations were seen in observational studies with intakes of 5.7 and 6.7 g/day (Refs. 18 and 21).

C. International Recommendations and Regulatory Initiatives

Several national and international government bodies have recently made recommendations or taken regulatory initiatives on *trans* fatty acids. Internationally, a joint Food and Agriculture Organization/World Health Organization (FAO/WHO) consultation recently addressed *trans* fatty acids. In 1993, they recommended (Ref. 31):

Governments should limit claims concerning the saturated fatty acid content of foods which contain appreciable amounts of *trans* fatty acids and should not allow foods that are high in *trans* fatty acids to be labeled as being low in saturated fatty acids.

The Department of Health, United Kingdom (UK) wrote in 1994 (Ref. 32):

We recommend that, on average, *trans* fatty acids should provide no more than the current average of about 2% of dietary energy and that consideration should be given to ways of decreasing the amount present in the diet.

At this level of intake, a 2,000 calorie diet would provide a daily intake of 4.4 g of *trans* fatty acids.

In 1996, the government of Canada proposed that certain definitions for nutrient content claims be revised to take into account the *trans* fatty acid composition of foods for which claims were made (Ref. 33). In 1998, Canada presented its proposed revisions to the criteria for nutrient content claims (Ref. 41).

Canada proposed to revise the definition of ''saturated fat free'' to less than 0.2 g saturated fatty acids and less than 0.2 g *trans* fatty acids per reference amount and per labeled serving and the definition of ''low saturated fat'' to not more than 2 g saturated and *trans* fatty acids combined per reference amount and per labeled serving and per 50 g if the reference amount

is 30 g or 30 milliliters or less, and not more than 15 percent of energy from saturated and *trans* fatty acids combined per reference amount and per labeled serving.

For the claim ''reduced saturated fat,'' Canada proposed that the product contain at least 25 percent less saturated fatty acids and, where present, at least 25 percent less *trans* fatty acids per reference amount (unless the *trans* fatty acid content is less than 0.2 g per reference amount and per labeled serving) than the reference food and the reference food must not meet the compositional criteria for ''low in saturated fatty acids.''

Canada proposed to define ''*trans* fatty acids free'' as less than 0.2 g *trans* fatty acids per reference amount and per labeled serving and the food must meet the compositional criteria for ''low in saturates.'' For ''reduced *trans* fatty acids,'' Canada proposed that the product contain at least 25 percent and at least 1 g less *trans* fatty acids per reference amount than the reference food and the content of saturated fatty acids must not be increased in comparison to the reference food.

D. Conclusions

Reports from the Federal Government and the NAS in the late 1980's concluded that *trans* fatty acids did not appear to have deleterious health effects. However, the 1995 Dietary Guidelines for Americans recognized that *trans* fatty acids may raise blood cholesterol levels although not as much as saturated fat (Ref. 6). In addition, the NCEP publication entitled ''Second Report of the Expert Panel on Detection, Evaluation and Treatment of High Blood Cholestorol in Adults'' stated that recent research indicates that *trans* fatty acids raise serum LDL–C levels (the major dietary risk factor for CHD) nearly as much as cholesterol-raising saturated fatty acids (Ref. 5).

Based on an independent evaluation of studies cited in the petitioner's submission, as well as recent studies in humans identified by a supplemental literature search, the agency concludes that controlled intervention studies in different population groups in the United States and other countries consistently indicate that consumption of diets containing *trans* fatty acids, like diets containing saturated fats, results in increased serum LDL–C compared with consumption of diets

containing *cis*-monounsaturated or *cis*-polyunsaturated fat sources. These findings are consonant with findings from observational studies among free-living persons in the United States and other countries.

The magnitude of the effect of *trans* fatty acids on serum LDL–C compared to the increase resulting from consumption of diets containing saturated fat is not known; its estimation is complicated by the different dietary conditions among studies. Estimates of mean dietary intake of *trans* fatty acids by the U.S. population are similar to the levels of *trans* fatty acids consumed in four intervention trials in the United States in which serum LDL–C was adversely affected and in which *trans* fatty acid contents of the diets were determined by chemical analysis (9 and 13 g/day, 9.7 and 12.9 g/day, 12.5 g/day, and as low as 7.6 g/day) (Refs. 12, 13, 34, and 82). Statistically significant associations between *trans* fatty acids intakes and increases in serum LDL–C concentrations among free-living populations were observed with intakes of 5.7 and 6.7 g/day (Refs. 19 and 21).

Estimates of dietary intake of *trans* fatty acids of the U.S. population by the various approaches described previously and the estimated levels of *trans* fatty acids consumed in intervention trials in which serum LDL–C was adversely affected are similar. Therefore, FDA concludes that under conditions of use in the United States, consumption of *trans* fatty acids contributes to increased serum LDL–C levels, which increases the risk of CHD. This conclusion is consonant with recent reports of other government and scientific bodies discussed previously. Moreover, the similar impact on LDL–C evidenced for *trans* fatty acids, as is known for saturated fatty acids, warrants serious attention from a public health perspective. Thus, the agency finds that addressing *trans* fatty acids in nutrition labeling and claims is important to public health.

V. Proposed Regulations

A. Nutrition Labeling

1. Inclusion of *Trans* Fatty Acids in Nutrition Labeling

FDA received approximately 1,000 letters in response to the petition. Many of the letters were form letters from consumers in support of the petition. One comment from the tropical oil industry supported the disclosure of *trans* fatty acid content information but recommended that *trans* fatty acids be declared as a separate line item in the nutrition label. FDA also received letters from trade associations representing the edible fats and oil industries, food manufacturers, and nutrition and public health associations. These letters generally disagreed with the petition and opposed modification of existing food regulations to include consideration of *trans* fatty acids. These comments, dating back to 1994, reported that data were inadequate to assess the overall impact of *trans* fatty acids on health, especially at the levels consumed.

Section 403(q) of the act, which was added by the 1990 amendments, states that a food shall be deemed to be misbranded if, with certain exceptions, it fails to bear nutrition labeling. Congress enacted this statute in recognition of the important role diet plays in the maintenance of good health. Congress acted shortly after the publication of two reports (Refs. 2 and 4) that concluded that scientific evidence substantiated an association between dietary factors and rates of chronic disease. Without specific nutrition information on the labels, however, consumers were unable to determine how individual foods fit into dietary regimens that adhered to the dietary guidance in the reports. Accordingly, the 1990 amendments mandated nutrition labeling on most foods to provide consumers with information about specified nutrients that would help them choose more healthful diets, as well as to create an incentive to food companies to improve the nutritional qualities of their products.

With an appreciation of the evolving nature of nutritional science, Congress added section 403(q)(2) to the act that provides for nutrients to be added or deleted from the list of required

nutrients in nutrition labeling if the Secretary (and, by delegation, FDA) finds such action necessary to assist consumers in maintaining healthy dietary practices.

When FDA issued the current nutrition labeling regulations on January 6, 1993, it required saturated fat to be listed. Current regulations also require monounsaturated fatty acids and polyunsaturated fatty acids to be listed when claims are made about fatty acids or cholesterol. Their listing is voluntary at all other times. For nutrition labeling purposes, monounsaturated and polyunsaturated fatty acids are defined as the *cis* isomers, i.e., *cis*-monounsaturated and *cis, cis*-methylene-interrupted polyunsaturated fatty acids (§ 101.9(c)(2)(ii) and (c)(2)(iii)).

The listing of saturated fat is important information for consumers who are attempting to make dietary selections because of the positive relationship between saturated fat intake and increased serum LDL–C levels. Based on its review of the available scientific literature (see section IV.B of this document), FDA concludes that the scientific evidence consistently shows that consumption of *trans* fatty acids also contributes to increased serum LDL–C levels. Under current regulations for the Nutrition Facts panel, *trans* fatty acids are included in the declaration of total fat but are not included in the declaration of types of fatty acids (i.e., saturated, monounsaturated, and polyunsaturated fatty acids). Therefore, their presence in a food can only be estimated by subtraction, i.e., by subtracting the sum of saturated, monounsaturated, and polyunsaturated fatty acids from the value declared for total fat. This calculation can only be made when monounsaturated and polyunsaturated fatty acids are listed and is too cumbersome for most consumers to be expected to accomplish. Therefore, the food label is not helpful, and may be misleading, to consumers seeking to purchase and consume foods that do not contain cholesterol-raising fats because information on *trans* fatty acids is not readily available. Accordingly, the agency is persuaded that it would be beneficial for food labels to include *trans* fatty acid content in providing nutrition information so that consumers will not be misled about the possible impact of a product on the risk of CHD. Consequently, in accordance with section 403(q)(2)(A) of the act, FDA is proposing

that information on *trans* fatty acids be added to the nutrition label to assist consumers in maintaining healthy dietary practices.

Four approaches for declaring *trans* fatty acids are included in the petition, its amendment, and comments. These are: (1) Include *trans* fatty acids with saturated fat and call the total value ''saturated fat;'' (2) include *trans* fatty acids with saturated fat, call the total value ''saturated fat,'' and add an asterisk after the term ''saturated fat'' when the food contains *trans* fatty acids that refers to a footnote stating ''Contains _____ g *trans* fat;'' (3) include *trans* fatty acids with saturated fat and call the total value ''saturated + *trans* fat;'' and (4) list *trans* fatty acids separately under saturated fat. In addition, the agency considered a fifth approach that combines two of these four approaches.

The agency considers the options that would combine saturated fatty acids and *trans* fatty acids into one numeric value to be the most useful way of preventing consumers from being misled about the possible impact of a food containing *trans* fatty acids on the risk of CHD. More specifically, the agency considers the option that would identify the combined amount as ''Saturated fat*'' with the asterisk referring to a footnote indicating the quantity of *trans* fat included in that amount to be the most helpful and least confusing approach for declaring *trans* fatty acids.

FDA does not prefer the petitioner's original approach of including *trans* fatty acids in the definition of saturated fat in § 101.9(c)(2)(i). This method would not inform consumers that the declared value included *trans* fatty acids or provide them with information on the *trans* fatty acid content of the food. In addition, amending the regulatory definition of saturated fat would be scientifically inaccurate because *trans* fatty acids are not saturated, i.e., they contain double bonds. Current regulations define saturated fatty acids as ''the sum of all fatty acids containing no double bonds.'' The proposed approach would maintain this chemical definition.

Also, one of the principles used by the agency in establishing nutrient content claims is that the nutrient must be declared in the nutrition label so that the claim is verifiable by reference

to the nutrition label. Accordingly, establishing a definition for "*trans* fat free" would be precluded if the *trans* fatty acid content of the product were not mentioned in the nutrition label.

FDA is also not proposing the petitioner's third amended approach of listing "saturated + *trans* fat" in one line of the nutrition label because listing "saturated + *trans* fat" with one value representing their combined weights does not enable consumers to know the content of either. Furthermore, this approach would increase the economic burden on industry by requiring label changes for all foods, even those that do not contain *trans* fat.

The agency also considered the approach of listing *trans* fatty acids as a separate line item under saturated fat. This approach would prevent consumers from misclassifying *trans* fatty acids as saturated fats, when, in fact, they are chemically mono- and polyunsaturated fatty acids. However, a great many consumers (almost 90 percent of consumers in a 1995 survey (Ref. 81)) do not understand that *trans* fatty acids raise serum LDL–C levels. Therefore, listing *trans* fats on a separate line would not be helpful in assisting them to maintain healthy dietary practice. Indeed, this approach has the potential of confusing consumers by undermining the messages in the Dietary Guidelines for Americans (Ref. 6) and NCEP (Ref. 5) that have focused on saturated fat. FDA does not want to distract consumers from years of consumer education messages about saturated fat, especially because the average intake of saturated fat exceeds the average intake of *trans* fat by about fivefold (approximately 25 g versus 5 g/day, respectively) (Ref. 26). Thus, FDA tentatively concludes that it is preferable for the two types of cholesterol-raising fats to be labeled in a manner that emphasizes saturated fats. In this way, consumers will be able to utilize their knowledge of saturated fat in making food selections. However, FDA requests comments on this tentative conclusion and whether it would be preferable to make *trans* fats a mandatory separate line, when present, because the magnitude of change in LDL–C may differ between the two types of fats.

Finally, the agency considered the two remaining approaches to not have the weaknesses of the three approaches discussed previously in this section. One of these approaches combines two

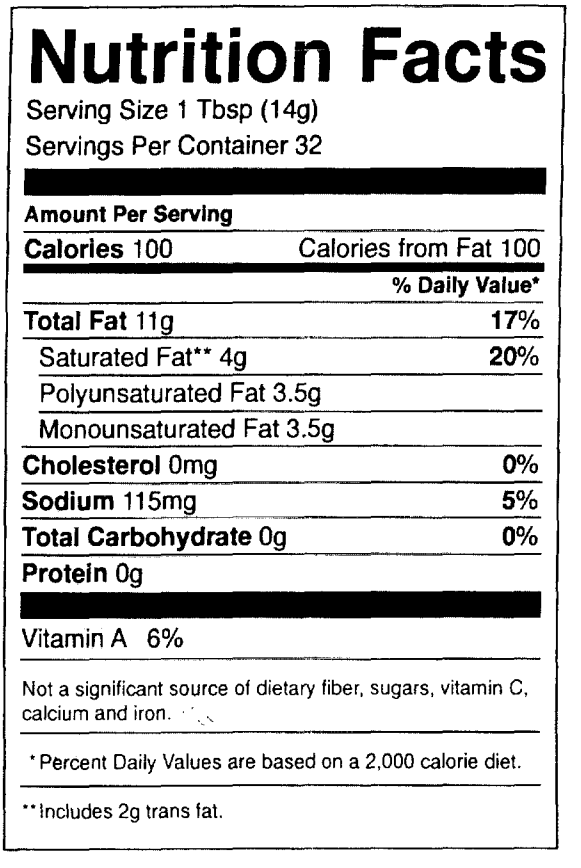
options suggested by the petitioner, i.e., using the name ''Saturated + *Trans* Fat'' and using an explanatory footnote stating the individual amounts of saturated fat and *trans* fat in the product. The amount of grams declared and the %DV would continue to be based on the combined value. This approach would give saturated fat and *trans* fat equal prominence and would further ensure that consumers are aware of the inclusion of *trans* fats in the amounts declared. It also may not confuse consumers into believing that *trans* fats are the same as saturated fats. FDA is concerned, however, that this approach could confuse consumers who do not yet know what *trans* fatty acids are or know about their impact on health and, therefore, could diminish the usefulness of the nutrition label and reduce health benefits. In addition, it could lead to increased costs for firms with products that do not contain *trans* fatty acids if such products' labels were required to indicate that they contained no *trans* fat. FDA requests comment on this possible approach, including whether FDA's concerns about potential consumer confusion are warranted and, if so, whether a consumer education program could address potential consumer confusion.

The other of these approaches is the petitioner's amended approach of declaring the total value of saturated fat and *trans* fatty acids following the term ''Saturated fat*'' with an explanatory footnote stating the amount of *trans* fatty acids included in the total value. This approach is beneficial because consumers are unlikely to be confused about the cholesterol-raising potential of the food, because the value declared for saturated fats will include *trans* fatty acids, and consumers will also have access to information on the actual amount of *trans* fatty acids present in a serving of the food. As stated previously, this approach also builds on the extensive work done by public health programs, most notably the NCEP. However, this approach may confuse consumers and lead some to misclassify *trans* fatty acids as saturated fats. FDA requests comments on whether this approach provides consumers with clear information on the presence of and distinction between *trans* and saturated fats. In balance, the agency tentatively concludes that this approach would be the more effective way of informing consumers of the *trans* fatty acid content of foods.

For the reasons discussed above, FDA is proposing to amend § 101.9(c)(2)(i) to require that the statement of the saturated fat content of the food declare the number of grams of saturated and *trans* fatty acids combined per serving. For ease of administration, the agency is subdividing current § 101.9(c)(2)(i), with § 101.9(c)(2)(i)(A) directed at format and rounding requirements and § 101.9(c)(2)(i)(B) directed at the use of the asterisk and footnote when *trans* fatty acids are, or are not, present. In § 101.9(c)(2)(i)(B), the agency is proposing that the footnote state ''Includes _____ g *trans* fat'' with the option of using the term ''*trans* fatty acids'' instead of ''*trans* fat'' (see sample label in Fig. 1). The petitioner had suggested the word ''contains'' rather than ''includes;'' however, the agency is concerned that the word ''contains'' may not convey the idea that the amount specified in the footnote is included in the numerical value declared. The word ''includes'' is more specific, although either word would be acceptable when the product does not contain *trans* fats, that is, contains less than 0.5 g of *trans* fats per reference amount.

In recognition of the economic impact of changing food labels to incorporate *trans* fatty acid information, however, FDA does not believe there is a need to change labels of products that do not contain *trans* fatty acids and that do not make claims about fatty acids or cholesterol. Consequently, FDA is proposing in § 101.9(c)(2)(i)(B) to allow manufacturers to use the footnote ''Includes (or contains) 0 g *trans* fat'' or ''Contains no *trans* fat'' on these labels on a voluntary basis. This footnote would not be required when there is no *trans* fat in the food unless fatty acid or cholesterol claims are made.

Figure 1



Nutrition Facts

Serving Size 1 Tbsp (14g)
Servings Per Container 32

Amount Per Serving

Calories 100	Calories from Fat 100
	% Daily Value*
Total Fat 11g	**17%**
Saturated Fat** 4g	**20%**
Polyunsaturated Fat 3.5g	
Monounsaturated Fat 3.5g	
Cholesterol 0mg	**0%**
Sodium 115mg	**5%**
Total Carbohydrate 0g	**0%**
Protein 0g	

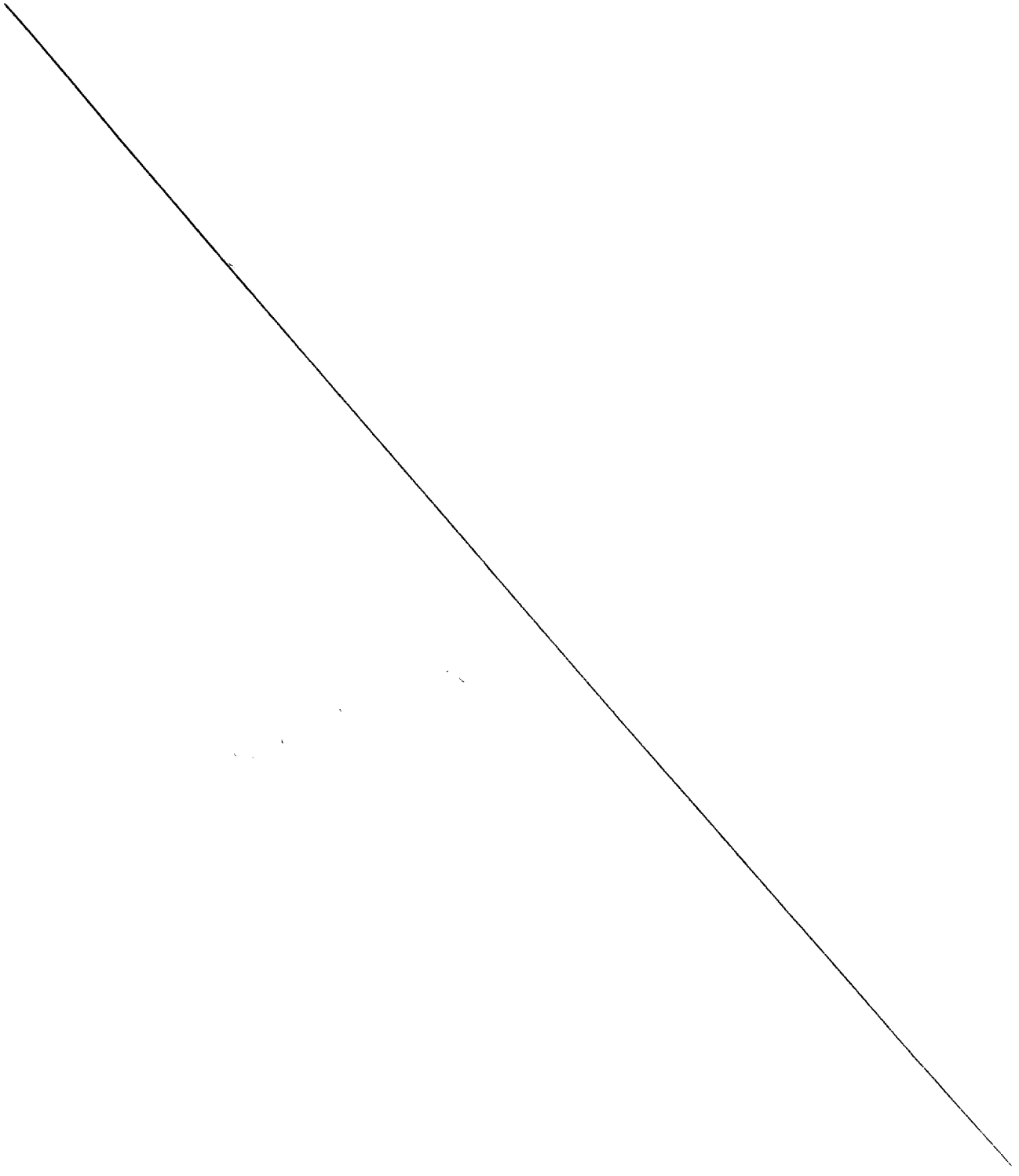
Vitamin A 6%

Not a significant source of dietary fiber, sugars, vitamin C, calcium and iron.

*Percent Daily Values are based on a 2,000 calorie diet.

**Includes 2g trans fat.

To maintain consistency in the nutrition labeling of conventional foods and of dietary supplements, the agency is also proposing to amend § 101.36(b)(2)(i) and (b)(2)(iii) (21 CFR 101.36(b)(2)(i) and (b)(2)(iii)) to specify that, when present, *trans* fatty acids are to be incorporated in the nutrition labeling of dietary supplements in the same manner as for conventional foods.



FDA tentatively concludes that the current regulations that consider only saturated fat when calculating the %DV do not help maintain healthy dietary practices, a goal set forth in the 1990 amendments, because *trans* fatty acids, which FDA has concluded also increase LDL–C, are not considered. If *trans* fatty acids are not considered, consumers who make food choices on the basis of saturated fat content with the intention of reducing their risk of CHD may be misled by the declared %DV.

For the past 20 years, a wide variety of consensus reports have recommended that Americans consume no more than 30 percent of calories from fat (Refs. 5, 6, 54, and 55). Many of these reports go on to recommend that saturated fat account for less than 10 percent of calories with monounsaturated and polyunsaturated fatty acids furnishing the remaining calories from fat (Refs. 5 and 56). The Daily Value for saturated fat was calculated on the basis of these recommendations (58 FR 2206 at 2219, January 6, 1993).

Trans fatty acids have not been considered in these dietary recommendations because their intakes were relatively low at the time these recommendations were made and their link to increased risk of CHD has been relatively recent. At this time, the public health and scientific associations that are the source of these recommendations have not indicated what impact the recent research on *trans* fats might have on the recommendations. However, the agency does not believe that it should increase the percentage of total calories from fat (i.e., from 30 percent or less to some higher value) when adding *trans* fat to the Daily Value. Therefore, FDA finds it necessary to consider the placement of *trans* fatty acids within the three categories of fatty acids that are addressed in the recommendations (i.e., saturated fatty acids, monounsaturated fatty acids, or polyunsaturated fatty acids) to ensure that consumers are not misled by label statements.

Dietary recommendations to limit saturated fat to less than 10 percent of calories were an attempt to limit the amount of fats known to have adverse effects on blood lipids. Evidence has accumulated that *trans* fatty acids have physiologic effects similar to saturated fats and *trans* fatty acids in foods are used functionally to replace saturated fat. The agency, therefore, tentatively

concludes that it is reasonable to include *trans* fatty acids in the %DV for saturated fat. Doing so, however, would have the effect of lowering the DV for saturated fat on labels of food products containing both saturated and *trans* fats since the DV (20g) would relate to the combined amounts of each. FDA will consider amending its approach if the public health and scientific organizations that are the source of current dietary recommendations arrive at different conclusions. Including *trans* fats in calculations of the %DV listed for saturated fat is also the logical outcome of having the quantitative amounts of these two types of fatty acids declared together in the nutrition label. Calculating the %DV on the basis of a quantitative value other than the one declared could be confusing to consumers. Comments are requested on this approach. In addition, comments are requested on whether there is a basis for developing a DV for *trans* fats if comments were to convince the agency to require a separate line for *trans* fat, and how a DV for *trans* fat should affect the DV's for total fat and saturated fat. Inasmuch as no authoritative bodies have recommended values that could be used as a basis for developing a DV for *trans* fat, would it be sufficient to list the quantitative amount of *trans* fat, with no %DV, as now occurs with listings of mono- and polyunsaturated fats? It should be noted that, without a DV for *trans* fat, consumers would not be able to put the quantitative amount in the context of a daily diet, and so would not be able to judge the magnitude of the amount present in relation to usual or recommended intake levels.

Based on these tentative conclusions, FDA is proposing to include *trans* fats in calculations of the %DV listed for saturated fat. Accordingly, FDA is proposing to amend § 101.9(d)(7)(ii) by adding the sentence "When *trans* fatty acids are present in a food, the percent for saturated fat shall be calculated by dividing the amount declared on the label for saturated fat, which includes *trans* fatty acids, by the DRV for saturated fat."

3. Other Issues

a. *Definition.* In revising § 101.9(c)(2)(i) to require the inclusion of *trans* fatty acid content in the declared amount of saturated fat, FDA is proposing to define *trans* fatty acids as "unsaturated

fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration.'' This proposed definition is consistent with the way that *cis* isomers of polyunsaturated fatty acids are defined in § 101.9(c)(2)(ii) and (c)(2)(iii).

b. *Methodology.* Infrared spectroscopy (IR) and capillary gas chromatography (GC) are the methods used for the determination of *trans* fatty acids. IR is the classical method used for the determination of total *trans* fatty acids with isolated *trans* double bonds, while GC methods are used for determination of fatty acid composition. The Official Methods of the Association of Official Analytical Chemists (AOAC) and Official Methods and Recommended Practices of the American Oil Chemists Society (AOCS) that are applicable to the determination of *trans* fatty acids are described in Appendix B of this document (Refs. 42 through 50). The official method number, title, definition, scope and applicability of each method, taken directly from the published method, are included. Specific comments by FDA chemists knowledgeable in application of these methods are also included.

Currently, the method of choice for IR determinations is AOCS Recommended Practice Cd 14d-96 (number 4 in Appendix B) (Ref. 45) and for GC determinations is AOCS Official Method Ce 1f-96 (number 5 in Appendix B) (Ref. 46). IR methodology can be used to determine *trans* isomers in oils, margarines, shortenings, and other partially hydrogenated fats and oils with a limit of quantitation of about 1 percent *trans* as percent of total fat. When *trans* fat levels are less than 1 percent of total fat, they can be accurately determined by GC. GC methods provide more sensitivity but require more time. None of the IR or GC methods have been collaboratively studied for foods other than fats and oils. It is likely that the lower limits of quantitation for these methods will be higher for complex matrices, such as processed multi-ingredient foods, than for oils and other fats.

Trans fatty acid values reported in the nutrition label should utilize compliance procedures in § 101.9(g) that take normal variability due to production processes into account.

of a saturated fat free claim, the agency believes that it would be misleading for products that contain

c. *Increments*. With respect to how to declare the content of *trans* fatty acids in the footnote ''Includes _____ g *trans* fat,'' FDA believes that the methodology discussed previously supports declaring the amount per serving in the same increments specified in § 101.9(c)(2) for total fat, saturated fat, polyunsaturated fat, and monounsaturated fat, i.e., to the nearest 0.5 (1/2) g increment below 5 g and to the nearest gram increment above 5 g. If the serving contains less than 0.5 g, the content shall be expressed as zero g (i.e., ''0'' g) in the footnote, if the footnote is used.

d. *Type size*. FDA also is removing the phrase ''in the same type size'' in § 101.9(c)(2)(i) where it refers to the size of the statement ''Not a significant source of saturated fat.'' In the technical amendments of August 18, 1993 (58 FR 44063 at 44066), the agency did not include footnotes in the types of information that must use 8 point type under § 101.9(d)(1)(iii). Therefore, under § 101.9(d)(1)(iii), 6 point type is sufficient for this statement and the proposed statement ''Includes _____ g *trans* fat.''

B. Nutrient Content Claims

A number of comments agreed with the petitioner's request that the saturated fat criteria for nutrient content claims should be amended to refer to the level of saturated and *trans* fat combined. Other comments disagreed. One comment suggested that consumer research be initiated to evaluate consumer understanding about *trans* fatty acids before such changes are considered. Another comment stated that the key question of whether *trans* fatty acids have an independent cholesterol-raising effect must be answered before the agency considers changes in food labeling for *trans* fatty acids.

As mentioned, the agency already has recognized that *trans* fatty acids should be considered with respect to the claim ''saturated fat free.'' In the nutrition labeling final rule implementing the 1990 amendments, the agency stated that because:

trans fatty acids raise LDL–C, FDA tentatively concludes that it is reasonable to consider the *trans* fatty acid content of products that bear these types of nutrient content claims to prevent such claims from being misleading.

1. Saturated Fat Claims

a. *Saturated fat free claims.* With respect to the claim ''saturated fat free,'' the agency has considered the petitioner's request that the definition be amended to be less than 0.5 g of saturated fat and *trans* fat combined. The agency agrees with the petitioner that products bearing this claim should be free of components that significantly raise serum cholesterol. However, the agency does not agree that the level of 0.5 g should refer to the sum of saturated fat and *trans* fats combined because it is not possible to determine, for reasons of sensitivity, if a sample contains less than 0.5 g of both saturated and *trans* fat combined.

In defining ''free'' levels of nutrients, the approach used by the agency has been that the level of a nutrient that is defined as ''free'' should be at or near the level of detection for the nutrient in foods and should be dietetically trivial or physiologically inconsequential (56 FR 60478 at 60484, November 27, 1991). In the nutrient content claims final rule, the agency established the ''free'' level of saturated fat at less than 0.5 g per serving because the majority of the comments that addressed this issue stated that a lower value cannot be reliably quantified (58 FR 2302 at 2332). With respect to *trans* fat, the nutrient content claims final rule stated that 1 percent of total fat was the appropriate criterion for *trans* fat because analytical methods for measuring *trans* fat below that level were not reliable. As discussed in section I of this document, comments objected to this criterion and, in response to these comments, the agency changed the *trans* fat criterion to less than 0.5 g because this level can be reliably determined analytically and is consistent with the definition of ''free'' for fat and saturated fat (58 FR 44020 at 44027, August 18, 1993).

The petitioner's suggestion that the definition of ''saturated fat free'' be changed to less than 0.5 g of saturated and *trans* fat combined is not analytically feasible because it would require

accurate measurement of both saturated fat and *trans* fat at levels significantly below 0.5 g. In the absence of more sensitive methods, which the petitioner did not provide, it is not appropriate for the agency to set criteria that cannot be adequately analyzed. Consequently, the agency is not proposing to change the criteria in § 101.62(c)(1)(i) of less than 0.5 g of saturated fat and less than 0.5 g of *trans* fat for the ''saturated fat free'' claim. The agency notes that expressing these criteria collectively as ''less than 1.0 g of saturated fat and *trans* fat combined'' is not preferable because if, for example, one of the types of fatty acids were present at 0.7 g, it would not be possible to determine if the combined amount were less than 1.0 g because amounts of less than 0.3 g cannot be reliably measured. The agency is willing to reconsider the criteria for this definition in the future if more sensitive methodologies become practical for routine analyses.

b. *Low saturated fat claims*. With respect to ''low saturated fat,'' the petitioner requested that the limit of ''1 g or less of saturated fatty acids'' in § 101.62(c)(2)(i) be amended to refer to ''1 g or less total of saturated and *trans* fat combined.'' FDA agrees that the level of *trans* fat should be limited in foods bearing this claim because consumers may assume that the claim refers to all fats that adversely affect serum LDL–C levels. However, FDA does not agree that this claim should be based on the sum of saturated fat and *trans* fat combined because, as previously discussed, it is not possible to reliably measure amounts of either type of fat at values below 0.5 g. Accordingly, if a food contains 0.8 g of saturated fat, there could be uncertainty about whether or not it contained 1 g or less of saturated and *trans* fat combined if the amount of *trans* fat were below 0.5 g.

Consequently, the agency tentatively concludes that separate criteria need to be established for saturated fat and for *trans* fat in the definition of ''low saturated fat.'' However, decreasing the level of saturated fat to accommodate a *trans* fat criterion (e.g., 0.5 g or less of saturated fat) is not feasible because there would be too little difference between the lowered level and the ''free'' level of saturated fat (i.e., less than 0.5 g).

Given this constraint, the agency tentatively concludes that the saturated fat criterion for ''low saturated fat'' claims should remain at 1 g or less per reference amount. Therefore, FDA proposes that the *trans* fat criterion be less than 0.5 g, the proposed ''free'' level of *trans* fat. This proposed action would allow foods that contain insignificant levels of *trans* fats to continue to qualify for ''low saturated fat'' claims.

The current definition for ''low saturated fat'' includes a second criterion that the claim not be used on foods that contain more than 15 percent of calories from saturated fat. The petitioner requested that this criterion be amended to require that the food contain not more than 15 percent of calories from saturated fat and *trans* fat combined.

This second criterion was used to prevent misleading ''low'' claims on nutrient-dense foods with small serving sizes (58 FR 2302 at 2339). Since the amendments being proposed in this document would broaden the term ''saturated fat'' on the label to include both saturated and *trans* fatty acids, the agency tentatively concludes that it is reasonable to amend this criterion to include both types of fatty acids. While it was not feasible to combine saturated fat and *trans* fats in the quantitative requirements discussed previously, it is not a problem in this instance because the percent of calories can be calculated by multiplying the declared amount of saturated and *trans* fats combined (in grams) by the factor of 9 calories per gram, dividing by the total caloric content of a serving of the product, and multiplying by 100.

Accordingly, FDA is proposing to amend the definition of ''low saturated fat'' in § 101.62(c)(2)(i) to read: ''The food contains 1 g or less of saturated fat and less than 0.5 g of *trans* fat per reference amount customarily consumed and not more than 15 percent of calories from saturated fat and *trans* fat combined.'' Likewise, the agency is proposing to revise § 101.62(c)(3)(i) for meal products and main dishes to state that ''low saturated fat claims'' may be made on meal products and main dishes if the product contains 1 g or less of saturated fat and less than 0.5 g of *trans* fat per 100 g, and less than 10 percent calories from saturated fat and *trans* fat combined. The agency also proposes to change the term ''saturated fatty acids''

to the term ''saturated fat'' in these two paragraphs for consistency with other paragraphs of § 101.62(c).

It should be noted that the definition for the nutrient content claim ''healthy'' includes a criterion that the food meet the definition of ''low saturated fat'' (§ 101.65(d)(2)(i) (21 CFR 101.65(d)(2)(i))). It is conceivable that some products may currently meet the criteria for this claim, yet not meet the proposed criteria for ''low in saturated fat'' and, therefore, would no longer qualify for the ''healthy'' claim if the agency takes the action proposed herein. The same thing is true for health claims that require that a food bearing the health claim meet the requirements for the claim ''low in saturated fat'': dietary saturated fat and cholesterol and risk of coronary heart disease (§ 101.75(c)(2)(ii) (21 CFR 101.75(c)(2)(ii))); fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease (§ 101.77(c)(2)(ii)(B) (21 CFR 101.77(c)(2)(ii)(B))); and soluble fiber from certain foods and risk of coronary heart disease (§ 101.81(c)(2)(iii)(C) ((21 CFR 101.81(c)(2)(iii)(C))).

c. *Reduced saturated fat claims.* The agency has defined the term ''reduced saturated fat'' to mean that the saturated fat content of a food has been reduced by at least 25 percent compared to a reference food. The petition states that without a limit on the *trans* fat content of foods with ''reduced saturated fat'' claims, manufacturers could replace saturated fat with *trans* fat.

The agency has studied the petition's request that the ''reduced saturated fat'' claim be defined as ''at least 25 percent less of saturated and *trans* fatty acids combined per reference amount customarily consumed than an appropriate reference food.'' Based on its review of the available scientific literature (see section IV.B of this document) indicating that dietary *trans* fat, like saturated fat, increases serum LDL–C levels, the agency tentatively concludes that requiring a total reduction of at least 25 percent in saturated fat and *trans* fat combined is appropriate and would prevent consumers from being misled by claims indicating a reduction in saturated fats when there is not a meaningful reduction in the combined value of saturated and *trans* fats. The percent reduction would be calculated by subtracting the sum of the saturated and *trans* fats in the labeled

food (either the combined value declared on the nutrition label or the actual combined values before rounding (58 FR 44020 at 44024)) from the total of saturated and *trans* fat in the reference food, dividing by the total for the reference food, and multiplying by 100.

However, the agency believes that it is also appropriate to retain the requirement for at least a 25 percent reduction in saturated fat. Having only a single criterion that refers to the combined amount of saturated and *trans* fat would make it possible for foods with no reduction in saturated fat, or even an increase, to use the claim ''reduced saturated fat.'' For example, a food containing 4 g of *trans* fat and 2 g of saturated fat, could be modified to contain 2 g of *trans* fat and 2.5 g of saturated fat. The modified food would contain a total of 4.5 g of saturated and *trans* fat combined, which would mean that the total has been reduced by 25 percent, even though the saturated content would be increased by 25 percent. The agency tentatively concludes that it is misleading to allow a food that is reduced in this manner to bear the claim ''reduced saturated fat.'' Therefore, FDA is proposing that the definition of ''reduced saturated fat'' in § 101.62(c)(4)(i) read: ''The food contains at least 25 percent less saturated fat and at least 25 percent less saturated fat and *trans* fat combined per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1).''

FDA points out that accompanying information is required with ''reduced claims.'' Section 101.62(c)(4)(ii)(A) requires information on the identity of the reference food and the percent (or fraction) that the saturated fat differs between the two foods, e.g., ''Reduced saturated fat. Contains 50 percent less saturated fat than the national average for nondairy creamers.'' This information must be declared in immediate proximity to the most prominent claim. Section 101.62(c)(4)(ii)(B) requires information on the amounts of saturated fat in the reference food and in the food, e.g., ''Saturated fat reduced from 3 g to 2 g per serving.'' This information generally must be declared adjacent to the most prominent claim or to the nutrition label. The agency is proposing no changes in these provisions. Accordingly, as proposed, the accompanying information would refer to the actual amount of saturated fat in the food, not to the amount declared in the nutrition label, when

that value includes *trans* fats. For example, if a reference food contained 4 g of saturated fat and this amount is reduced to 2 g in the product bearing the claim, this would be stated as a 50 percent reduction in saturated fat from 4 g to 2 g, regardless of the amount of *trans* fat present. As discussed, if this rule is finalized as proposed, foods qualifying for this claim would also have to meet the hidden (i.e., not visible to the consumer) criterion of at least a 25 percent reduction in saturated fat and *trans* fat combined.

2. *Trans* Fat Claims

Although the petitioner did not address the use of *trans* fat claims, the agency's consideration of the subject petition has prompted the agency to consider the usefulness of such claims. As discussed previously, FDA concludes that *trans* fats contribute to increased serum LDL–C levels. In light of this conclusion, FDA is considering whether providing for the use of a ''*trans* fat free'' claim would assist consumers in maintaining healthy dietary practices by allowing them to readily identify foods free of fats known to increase the risk of CHD or if it would confuse them by detracting from the saturated fat message of the NCEP and other groups. The agency also is considering whether the claim is needed to provide an incentive to the food industry to remove *trans* fats from foods currently containing them. The agency requests comments on the usefulness of such a claim in these contexts. In particular, is allowing manufacturers to use the footnote ''Contains no *trans* fats'' in the nutrition label when foods are free of *trans* fats sufficient to allow these foods to be identified readily by consumers? In addition, requiring inclusion of *trans* fat, when present, in the declaration of saturated fat will increase the amounts declared. Will avoiding this increased saturated fat declaration provide sufficient incentive to manufacturers to eliminate *trans* fats whenever possible or is the ''*trans* fat free'' claim also needed?

FDA is proposing a definition for ''*trans* fat free'' in this document to be able to receive comments on the particulars of the definition and, thus, to be able to proceed to a final rule if the comments support this action. If comments do not justify the need for this claim, the agency intends to withdraw the proposed definition.

In arriving at a proposed definition, the agency reviewed its general approach to defining ''free'' levels of a nutrient when implementing the 1990 amendments. At that time, FDA stated that the level of a nutrient that is defined as ''free'' should be at or near the reliable limit of detection for the nutrient in foods (56 FR 60478 at 60484, November 27, 1991). In technical amendments to the nutrition labeling final rules, FDA concluded that less than 0.5 g of *trans* fat meets this criterion. As a result, the agency required that foods bearing ''saturated fat free'' claims contain less than 0.5 g of *trans* fat per reference amount and per labeled serving (58 FR 44020 at 44027, August 18, 1993). Because analytical techniques for measuring *trans* fats continue to preclude more precise determination, the agency tentatively concludes that foods bearing the claim ''*trans* fat free'' should contain less than 0.5 g of *trans* fat per reference amount customarily consumed and per labeled serving.

Section 403(r)(2)(A)(vi) of the act states that a claim may not be made if the claim is misleading in light of the level of another nutrient in the food. In the case of a ''*trans* fat free'' claim, the agency tentatively concludes that it would be misleading for foods bearing the claim to contain measurable amounts of saturated fat because consumers would expect such products to be ''free'' of components that significantly raise serum LDL–C. Therefore, in addition to a *trans* fat criterion of less than 0.5 g, the agency believes that foods bearing a ''*trans* fat free'' claim should also meet the criterion for ''saturated fat free'' of less than 0.5 g of saturated fat per reference amount and per labeled serving (§ 101.62(c)(1)(i)). It should be noted that the level of ''saturated fat'' specified in regulations as a criterion for a ''*trans* fat free'' claim, or for any other claim, refers to the analytically determined amount of saturated fat in a food, not to the combined amounts of saturated and *trans* fat declared on the label.

Accordingly, the agency is proposing to add § 101.62(c)(6) to provide for the use of the claim ''*trans* fat free'' and its synonyms on the labels of foods, meal products, and main dishes. Consistent with other ''free'' claims, the synonyms proposed include ''free of *trans* fat,'' ''no *trans* fat,'' ''zero *trans* fat,'' ''without *trans* fat,'' ''trivial amount of *trans* fat,'' ''negligible source

of *trans* fat,'' or ''dietarily insignificant source of *trans* fat.'' In addition, the agency is proposing to allow for the synonymous use of the terms ''*trans* fat'' or ''*trans* fatty acids.''

Because the proposed levels for *trans* fat and saturated fat in proposed § 101.62(c)(6)(i) would result in ''*trans* fat free'' and ''saturated fat free'' claims being synonymous, foods that meet the criteria for the two claims would be able to use either claim or both claims simultaneously.

Consistent with parallel provisions for saturated fat in § 101.62(c)(1)(ii), the agency is proposing to add § 101.62(c)(6)(ii) that states that a food bearing a ''*trans* fat free'' claim shall contain no ingredient that is generally understood by consumers to contain *trans* fats unless the listing of the ingredient in the ingredient statement is followed by an asterisk (or other symbol) that refers to a statement below the list of ingredients that states, ''adds a trivial amount of *trans* fat,'' or other synonymous phrases. The agency tentatively concludes that this provision is needed because some consumers may be confused by the listing of ingredients such as partially hydrogenated oils, for example, on product labels that bear a ''*trans* fat free'' claim.

To ensure that ''*trans* fat free'' claims are not misleading by being used on foods that would not typically contain *trans* fats, and consistent with parallel provisions in § 101.62(c)(1)(iii) for saturated fat, the agency also is proposing to add § 101.62(c)(6)(iii) that states that a food bearing a ''*trans* fat free'' claim shall disclose when *trans* fats are not usually present in the food (e.g., ''Corn oil, a *trans* fat free food'').

The agency notes that it considers statements such as ''no hydrogenated oils'' or ''hydrogenated fat free'' to be implied claims that a product is free of *trans* fatty acids because, as described in section IV.A of this document, *trans* fatty acids are primarily the result of the hydrogenation process. In accordance with § 101.65(c)(3), such statements would be permissible on a food only if the food met the criteria for a ''*trans* fat free'' claim.

The agency specifically invites comments on the proposed definition of ''*trans* fat free'' and on the general usefulness of this claim.

FDA also considered, but rejected, proposing definitions for ''low *trans* fat'' and ''reduced *trans* fat.'' The agency has consistently required that definitions for ''low'' claims relate to the total amount of the nutrient recommended for daily consumption (56 FR 60439 and 58 FR 2302 at 2335). However, because consensus documents do not provide quantitative recommendations for daily intake of *trans* fats, FDA concludes that the claim ''low *trans* fats'' cannot be defined. In the case of the claim ''reduced *trans* fats,'' the agency is concerned that use of the claim could detract from educational messages that emphasize saturated fatty acids. However, any person who believes that such a claim is useful may petition the agency under § 101.69 (21 CFR 101.69).

The agency notes that proposing a definition for ''*trans* fat free'' in § 101.62(c)(6) necessitates consideration of the application of § 101.62(c) ''Fatty acid content claims'' to *trans* fatty acid claims. Current § 101.62(c) requires disclosure of total fat and cholesterol levels in proximity to saturated fat claims. Specifically, disclosure of total fat is required unless the food contains less than 0.5 g total fat when ''saturated fat free'' claims are made or 3 g or less total fat when ''low'' or ''reduced'' saturated fat claims are made. Likewise, disclosure of cholesterol is required unless the food contains less than 2 milligrams (mg) of cholesterol. These requirements are in response to sections 201(n), 403(a), and 403(r)(2)(A)(iv) of the act. Section 403(r)(2)(A)(iv) of the act requires disclosure of the cholesterol content of the food in immediate proximity to claims about the level of saturated fat. Similarly, FDA required disclosure of the amount of total fat adjacent to saturated fat claims because research suggested that consumers often did not differentiate between total fat and saturated fat content and, therefore, the level of total fat was a material fact necessary to prevent consumers from being misled about the total fat content of the food (56 FR 60478 at 60492 and 58 FR 2302 at 2340).

The agency believes that consumers are likely to purchase foods with claims about *trans* fats for the same purpose as they would purchase a food with claims about saturated fats, i.e., to help lower their CHD risk. Also, the agency does not believe that consumers are any more likely to differentiate between total fat and *trans* fat than between total fat and saturated fat. In fact, they

may be less likely to differentiate because there have been no public education programs aimed at making consumers aware of *trans* fats, and, consequently, fewer consumers can be expected to recognize the name "*trans* fat." Therefore, FDA tentatively concludes that it is reasonable to require disclosure statements about total fat and cholesterol with both types of fatty acid claims, and that doing so should prevent consumers from being misled about the level of total fat and cholesterol in foods bearing a "*trans* fat free" claim. Accordingly, the agency is proposing to amend § 101.62(c) to have it apply to *trans* fat claims as well as to saturated fat claims.

3. Cholesterol Claims

Under current regulations, cholesterol claims are prohibited when a food contains more than 2 g of saturated fat per reference amount (or per labeled serving size for meals and main dishes). The petitioner requested that this saturated fat threshold be amended to state that foods bearing cholesterol claims must contain "2 g or less of saturated and *trans* fatty acids combined."

The saturated fat threshold was introduced when implementing the 1990 amendments to prevent cholesterol claims from being misleading in light of the amount of saturated fat present in the food (58 FR 2302 at 2333). This action was issued in accordance with section 403(r)(2)(A)(vi) of the act. As discussed in section IV.B.2 of this document, FDA has concluded that *trans* fats have physiologic effects similar to saturated fats. Because of this effect, FDA tentatively concludes that it is appropriate for the saturated fat threshold for cholesterol claims to be the total of saturated and *trans* fats combined. At the 2 g level, the agency does not anticipate that concerns about the sensitivity of analytical methods will preclude calculation of the combined amount.

Accordingly, FDA is proposing to revise § 101.62(d)(1)(i)(C) and (d)(1)(ii)(C) to state that a "cholesterol free" claim may be made when the food contains 2 g or less of saturated fat and *trans* fat combined per reference amount customarily consumed or, in the case of a meal product or main dish product, 2 g or less of saturated fat and *trans* fat combined per labeled serving. The proposed change in § 101.62(d)(1)(ii)(C) also corrects a technical error because this section

currently reads ''less than 2 g of saturated fat'' and it should read ''2 g or less of saturated fat.'' Similar changes are proposed for ''low cholesterol claims' for foods and meals and main dishes in § 101.62(d)(2)(i)(B), (d)(2)(ii)(B), (d)(2)(iii)(B), (d)(2)(iv)(B), and (d)(3) and for ''reduced cholesterol'' claims for foods in § 101.62(d)(4)(i)(B) and (d)(4)(ii)(B) and for meals and main dishes in § 101.62(d)(5)(i)(B) and (d)(5)(ii)(B).

4. Lean and Extra Lean Claims

As requested by the petitioner and for the reasons noted previously for cholesterol claims, FDA is proposing to amend the definitions of ''lean'' and ''extra lean'' for foods and meal products to require that the saturated fat criterion now refer to the level for saturated fat and *trans* fat combined.

Therefore, FDA is proposing to revise § 101.62(e)(1) to state that seafood and game meat products may use the term ''lean'' if they contain less than 10 g total fat, 4.5 g or less saturated fat and *trans* fat combined, and less than 95 milligrams (mg) cholesterol per reference amount customarily consumed and per 100 g. Likewise, the agency is proposing to revise § 101.62(e)(3) to state that the term ''extra lean'' may be used on these foods if they contain less than 5 g total fat, less than 2 g saturated fat and *trans* fat combined, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g. Similar revisions are proposed for § 101.62(e)(2) and (e)(4), which address the use of the terms on labels or in labeling of meal and main dish products.

It should be noted that the regulation on the health claim regarding dietary lipids and cancer includes a criterion in § 101.73(c)(2)(ii) (21 CFR 101.73(c)(2)(ii)) that the food must meet the requirements for ''low fat'' in § 101.62, except that fish and game meats may meet the requirements for ''extra lean'' in § 101.62. Thus, some fish and game meat products that currently meet the criteria for this health claim may not be eligible if the proposed definition for the claim ''extra lean'' is issued.

C. Disqualifying and Disclosure Levels

The petitioner requested that FDA amend the disqualifying level for health claims and the disclosure level for nutrient content claims with respect to saturated fat. The petitioner also requested that § 101.14(a)(5) regarding disqualifying nutrient levels for health claims and the general disclosure requirements for nutrient content claims in § 101.13(h)(1) be amended by replacing ''4.0 g of saturated fat'' with ''4.0 g total of saturated and *trans* fatty acids combined.'' The petitioner requested similar changes for health claims for meal and main dish products in § 101.14(a)(5)(i) and (a)(5)(ii) and for nutrient content claims for these types of products in § 101.13(h)(2) and (h)(3). The petitioner maintained that health claims and nutrient content claims are misleading on products containing high levels of *trans* fatty acids, and that incorporating *trans* fatty acids criteria into these requirements serves to limit the potential for any such misleading claims.

The purpose of the disqualifying levels for health claims is to ensure that health claims cannot be made for products that contain nutrients in amounts that increase to persons in the general population the risk of a disease or health-related condition that is diet related (see section 403(r)(3)(A)(ii) of the act). For example, the disqualifying level for saturated fat ensures that a sodium and hypertension claim cannot be made for a product that contains high levels of saturated fat. Such a claim could lead consumers to believe that the product is useful in constructing a healthful total daily diet, when, in fact, it contains a high level of saturated fat, which increases the risk of heart disease.

For products bearing nutrient content claims, disclosure levels direct consumers to information about certain nutrients that are present in levels high enough to increase the risk of a diet-related disease or health condition. For example, a product may qualify for a ''good source of vitamin A'' claim yet contain high levels of cholesterol. The label for such a product must state ''See nutrition information for cholesterol content'' next to the claim. In this manner, the label draws

attention to the presence of cholesterol, and the claim is not misleading for failing to reveal a material fact about the consequences of consuming the food.

The 1990 amendments directed the agency to take into account the significance of the food in the total daily diet in determining disqualifying and disclosure levels. Accordingly, both disqualifying and disclosure levels were based on 20 percent of the Daily Reference Values (DRV's) for total fat, saturated fat, cholesterol, and sodium, taking into account the number of eating occasions and the number of foods containing these nutrients in the food supply (58 FR 2478 at 2493 and 2494). FDA adopted the 20 percent criterion because it provides a consistent and appropriate basis for defining the levels at which the presence of a particular nutrient may be undesirable (58 FR 2478 at 2493 and 2494). Applying the 20 percent criterion to saturated fat, which has a DRV of 20 g, resulted in a disqualifying and disclosure level of 4 g for saturated fat.

FDA is persuaded by the petitioner that the disqualifying and disclosure level of 4 g of saturated fat should be amended to be ''4 g total of saturated and *trans* fatty acids combined.'' As discussed previously, FDA has concluded that *trans* fatty acids have been shown to have physiologic effects on serum LDL–C similar to saturated fatty acids. Because of this effect, FDA believes that health claims and nutrient content claims would be misleading on products containing high levels of *trans* fatty acids. For this reason, FDA tentatively concludes that it is appropriate for the level to be the total of saturated and *trans* fatty acids combined. Having the saturated fat level be amended to incorporate *trans* fat is consistent with tentative conclusions in the discussion on Daily Value (section V.A.2 of this document) that it is reasonable to include *trans* fats in calculations of %DV for saturated fatty acids. Therefore, FDA is proposing that § 101.14(a)(5) regarding disqualifying nutrient levels for health claims and the general disclosure requirements for nutrient content claims in § 101.13(h)(1) be amended by replacing ''4.0 g of saturated fat'' with ''4.0 g of saturated fat and *trans* fat combined.'' FDA is proposing similar changes for health claims for meal and main dish products in § 101.14(a)(5)(i) and (a)(5)(ii) and

for nutrient content claims for these types of products in § 101.13(h)(2) and (h)(3). For consistency with others food labeling regulations, FDA also is proposing in § 101.14(a)(5), (a)(5)(i), and (a)(5)(ii) that the term ''per label serving size'' be changed to read ''per labeled serving size.''

In view of this proposed change, FDA considered whether the referral statement accompanying nutrient content claims on the labels of foods that contain more than 4 g of saturated fat and *trans* fat should read ''See nutrition information for saturated and *trans* fat content.'' FDA tentatively concludes that the statement ''See nutrition information for saturated fat content'' is sufficient because *trans* fat may not be present. Also, if *trans* fat were present, the amount declared for saturated fat would include the amount of *trans* fat in the food and would have a footnote stating this amount. However, under the proposed provisions, the agency would not object to the use of a statement that refers to both saturated fat and *trans* fat.

D. Vegetable Oil Claims

The petitioner requested that FDA require that the fat content in a product be low in both saturated and *trans* fatty acids if a vegetable oil claim is made. The petitioner argued that claims in restaurants that foods are cooked with ''100% vegetable oil'' are misleading when the oil contains high levels of total ''heart-unhealthy'' fat. The petitioner requested that § 101.65(c)(3) be amended to state that ''made with vegetable oil'' is an implied claim that the product is low in saturated and *trans* fatty acids combined.

The agency has stated that there are long established relationships between ingredients and nutrients that are covered under the definition of implied nutrient content claims (58 FR 2302 at 2372). FDA has issued warning letters regarding foods that bear label statements, such as ''100 percent vegetable oil,'' that imply that these ingredients have low levels of saturated fat when that is not true (58 FR 2302 at 2372). FDA has said that ingredient claims that make an implied representation about the level of a nutrient in a food should be considered implied nutrient content claims (58 FR 2302 at 2372). Section 101.65(c)(3), which addresses implied nutrient content claims, states, in part, that a claim ''that a food is made only with vegetable oil is a claim that the food

is low in saturated fat.'' Therefore, because the agency is proposing to amend the definition of ''low saturated fat'' in § 101.62(c)(2) to include a *trans* fatty acid criterion, FDA believes that the action requested by the petitioner has been addressed and it is not necessary to propose an additional amendment to § 101.65(c)(3). Generally, nutrient content claims for restaurant foods must comply with the same requirements as for retail foods (see 58 FR 2302 at 2386 and 61 FR 40320, August 2, 1996).

E. ''Partially Hydrogenated'' in Ingredient Statements

The petitioner stated that the term ''hydrogenated'' is meaningless to most consumers, but that consumers are familiar with the term ''saturated'' and associate it with fats that can raise blood cholesterol levels. The petitioner maintained that using the term ''saturated'' instead of the term ''hydrogenated'' would be more understandable to consumers and would further serve to highlight the presence of ''heart-unhealthy'' fats. Further, the petitioner argued that the term ''fully saturated'' or ''partially saturated'' accurately describes the nature of the hydrogenated fat after the chemical process of hydrogenation.

The agency has previously considered this issue. In the **Federal Register** of January 6, 1976 (41 FR 1156), the agency established the term ''partially saturated'' for oils that were partially hydrogenated for the purpose of ingredient labeling. In November 1976, based on requests from six trade associations representing the edible oils industry, FDA reversed itself and proposed to amend its regulations by substituting ''hydrogenated'' and ''partially hydrogenated'' for ''saturated'' when those modifying terms are required to accompany the name of a fat or oil ingredient on the labeled foods (41 FR 52481, November 30, 1976). The trade associations for the edible fats and oils industry contended that the terms ''saturated'' and ''partially saturated'' were confusing and misleading to consumers in that they tended to equate different oils that differ widely in their content of saturated fats. Data furnished by the trade associations showed that partially hydrogenated soybean oil has a lower saturated fatty acid content than unhydrogenated palm kernel oil, hydrogenated palm oil, and commercially blended shortenings. One association

stated that the partial hydrogenation of an oil that is low in saturated fats (e.g., cottonseed oil, soybean oil) results in a product containing less total saturated fat than a similar product made from a fat or oil that intrinsically has a much higher degree of saturation, such as animal fats, palm oil, or coconut oil (41 FR 52481). Based in part on this information, FDA required use of the term ''partially hydrogenated'' in its final rule on the label designation of fats and oils (43 FR 12856, March 28, 1978).

FDA has re-examined this issue considering the *trans* fat content as well as the saturated fat content of fats and oils. A review of the nutritional content of varied fats and oils shows that many partially hydrogenated oils contain lower amounts of saturated fatty acids and *trans* fatty acids combined than fats that are unhydrogenated (e.g., lard) (Ref. 40).

Therefore, the agency continues to believe that use of the terms ''saturated'' and ''partially saturated'' to describe fats and oils processed in a certain way may mislead consumers to equate fats and oils that, in fact, differ substantially in their content of ''heart-healthy'' fats. This misperception could cause consumers to avoid a processed oil, which would be required to be identified as ''partially saturated,'' and instead choose an unprocessed fat or oil, even though it may contain more saturated fatty acids than the combined amount of saturated fatty acids and *trans* fatty acids in another product.

The agency has stated that the purpose of the regulatory requirement in § 101.4(b)(14) is to distinguish in the name between unprocessed and processed fats or oils (43 FR 12856). The term ''hydrogenated'' more accurately makes this distinction because ''saturated'' describes a chemical characteristic of a fatty acid. All vegetable oils, whether processed or not, are at least partially saturated, that is, they contain some fatty acids that have only single bonds. However, a partially saturated oil is not necessarily partially hydrogenated and a partially saturated oil does not necessarily contain *trans* isomers. The terms ''hydrogenated'' and ''partially hydrogenated'' describe the chemical process of the addition of hydrogen to a natural fat or oil for functional reasons (see section IV.A of this document).

innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

A. Need for This Regulation

Current nutrition labeling regulations do not allow manufacturers to disclose information about the *trans* fat content in the nutrition label of their products. The regulations in § 101.9(c) read, in part, that ''No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label.'' Some of the nutrients listed are total fat, saturated fat, polyunsaturated fat (voluntary), and monounsaturated fat (voluntary). *Trans* fat is not included as either mandatory or voluntary and, therefore, no information about *trans* fat may be included in the Nutrition Facts panel.

Nutrient content claim regulations in § 101.62(a) read, in part, that ''A claim about the level of fat, fatty acid, and cholesterol in a food may only be made on the label or in the labeling of foods if: (1) The claim uses one of the terms defined in this section in accordance with the definition of that term.'' No such term is defined for *trans* fat.

This proposed regulation is needed to amend existing regulations to permit and require manufacturers to provide important health-related information to consumers regarding the amount of *trans* fat in food products. This regulation is also needed to amend existing regulations of claims that in some manner involve the amount of saturated fat so that the regulations set limits for *trans* fat and do not permit misleading claims.

B. Regulatory Alternatives

FDA has considered a number of regulatory alternatives regarding *trans* fat. FDA requests comment on the benefits, costs, and any other aspect of these (and any other) alternatives.

1. Take No New Regulatory Action

FDA could choose to deny the petition and take no new action in regard to *trans* fat. Taking no new regulatory action will be considered the baseline. Absolute benefits and costs are associated

with all regulatory options, including the baseline. Absolute benefits and costs can be thought of as the state of the world under various policy options. A regulatory assessment of an option measures the difference between the absolute benefits and costs of that option and the absolute benefits and costs of the baseline. Measured benefits and costs are therefore zero at the baseline.

FDA has not selected this option for three reasons. First, it found that *trans* fat increases the risk of CHD. Second, consumers would not be informed as completely as they could be by the nutrition label about the *trans* fat content of the food products that they consume. Third, claims that have limits for saturated fat and not for *trans* fat may be misleading.

Producers have limited incentives to reduce the *trans* fat content of food products because current regulations prohibit manufacturers from using the label to inform consumers about the *trans* fat content of their products. This lack of information about *trans* fat content results in increased *trans* fat consumption that is associated with an increased risk of CHD, as shown in the estimates of benefits when such information is provided. FDA believes that the proposed option minimizes any potential for diverting consumers' attention from the risk of CHD associated with saturated fat, while providing consumers with information on the *trans* fat content of food products. The proposed option also prevents misleading claims and provides producers with incentives to reduce the *trans* fat content of food products.

2. Take the Proposed Regulatory Action Described in Section V of this Document

The analysis beginning with section VI.C of this document estimates the benefits and costs of this alternative.

3. Propose to Permit the Voluntary Labeling of *Trans* Fat and to Permit *Trans* Fat Nutrient Content Claims

FDA could propose voluntary rather than mandatory labeling of *trans* fat and propose to allow *trans* fat claims. This alternative would directly address the difficulties posed by current regulations in providing information on *trans* fat content on the label. However, a voluntary rule is unlikely

to result in information on *trans* fat content being provided on the labels of any products with one or more grams of *trans* fat. Therefore, consumers would not have important nutrition information available to them on the labels of many products where it is most needed. Margarine makers know how to reformulate margarine to eliminate *trans* fat. Indeed, many margarine products have already been reformulated. Voluntary labeling coupled with claims could therefore possibly provide sufficient incentives to cause the makers of unreformulated margarine to reformulate their products. Makers of other food products containing *trans* fat, however, do not yet know how to reformulate their products. The agency believes that it is unlikely that voluntary labeling would provide sufficient incentive for reformulation of many other products. Although (as shown in section VI.D.6 of this document) reformulating these other food products is costly, the public health benefits generated by reformulating these products greatly exceed the costs. Because voluntary labeling leads to less reformulation and smaller health benefits than mandatory labeling, the net benefits would be lower for voluntary labeling than for the proposed rule.

Voluntary labeling would also require the listing of *trans* fat on a separate line in the Nutrition Facts Panel. The problems with a separate line for *trans* fat are discussed in the following paragraphs.

4. Alter the Proposed Regulatory Action—Propose Reporting of *Trans* Fat on a Separate Line Below Saturated Fat

FDA is proposing that the line in the Nutrition Facts panel for saturated fat report the total grams of saturated fat and *trans* fat combined, and that the combined amount be used to determine the %DV labeled for saturated fat. The saturated fat listing will be accompanied by an asterisk referring to a footnote in the Nutrition Facts panel indicating the amount of *trans* fat per serving in grams. Alternatively, FDA could propose the listing of *trans* fat on a separate line under saturated fat. In comparison with the proposed option, this alternative may make the *trans* fat content of the product more obvious to consumers and may provide more incentive to producers to reduce the amount of *trans* fat in food. This approach has the potential to confuse consumers by

undermining educational messages that focus on saturated fat. Also, without a daily value for *trans* fat, consumers might be unable to tell if the amount per serving is high or low.

If the agency were to require listing the amount of *trans* fat on a separate line in the Nutrition Facts panel, all labels would have to be changed—including those for products containing no *trans* fat. These additional labeling costs would have no additional benefits associated with them.

5. Alter the Proposed Regulatory Action—Propose to Report *Trans* Fat Differently than in the Proposal

FDA could propose to include *trans* fat with saturated fat, call the total value ''saturated fat,'' and not have the amount of *trans* fat declared in a footnote. This alternative would not divert consumers' attention from the saturated fat content of food products. At the same time, it would provide consumers with information on combined saturated and *trans* fat content and provide producers with incentives to reduce the level of both saturated and *trans* fat in their products. However, it would not provide consumers with information on either the *trans* fat content or the actual saturated fat content of food.

One of the principles used by FDA in establishing nutrient content claims is that the nutrient must be declared in the Nutrition Facts panel so that the claim is verifiable by reference to the Nutrition Facts panel. Accordingly, establishing a definition for ''*trans* fat free'' would be precluded if the *trans* fat content of the product were not mentioned in the Nutrition Facts panel.

Alternatively, FDA could propose to include *trans* fat with saturated fat and call the total value ''saturated and *trans* fat''. This approach would increase the economic burden on industry by requiring label changes for all foods, even those that do not contain *trans* fat. Moreover, consumers would not be able to determine the content of either saturated or *trans* fat, and saturated fat and *trans* fat content claims would not necessarily be verifiable by reference to the Nutrition Facts panel.

As a second alternative, FDA could propose to include *trans* fat with saturated fat and call the total value ''saturated and *trans* fat,'' with a footnote stating the individual amounts of saturated

fat and *trans* fat. This approach would lead to higher costs than the proposed regulatory action if it requires label changes for all foods, even those that do not contain *trans* fat.

6. Expand the Proposed Regulatory Action—Propose ''Low *Trans* Fat'' and ''Reduced *Trans* Fat'' Claims

The proposed rule would define a nutrient content claim for ''*trans* fat free.'' FDA could propose to define ''low *trans* fat'' and ''reduced *trans* fat'' claims. These claims would provide producers with additional incentive to reduce the amount of *trans* fat in food products. However, FDA has consistently required that definitions for ''low'' claims relate to the total amount of the nutrient recommended for daily consumption. Because consensus documents do not provide quantitative recommendations for daily intake of *trans* fat, FDA concludes that the claim ''low *trans* fat'' cannot be defined. In the case of ''reduced *trans* fat,'' the agency is concerned that use of the claim could detract from educational messages that emphasize saturated fat.

7. Expand the Proposed Regulatory Action—Propose Labeling at Food Service Establishments

Partially hydrogenated fats and oils are used extensively in the food service industry for baking and frying. For example, USDA data indicate that a single serving of french-fried potatoes from a fast food restaurant may contain over 3.5 g *trans* fat per 70 g serving (Ref. 40). If FDA were to require that content information about *trans* fat be provided in food service establishments, consumers could more easily make informed menu choices. However, FDA is not permitted to pursue this alternative. The 1990 amendments specifically preclude FDA from requiring nutrition labeling in food service establishments unless the food bears a nutrition claim or other nutrition information on its menu or other forms of labeling. If an establishment is making a claim for a food, the food must meet the criteria for the claim and the amount of nutrient that is the subject of the claim must be made available.

C. Benefits

To estimate the health benefits of the proposed rule, FDA is following the general approach used to estimate the health benefits for the implementation of the 1990 amendments (56 FR 60856 at 60869, November 27, 1991). Accordingly, FDA is estimating: (1) The changes in *trans* fat intakes that would result from labeling changes; (2) the changes in health states that would result from changes in *trans* fat intakes; and (3) the value of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits. FDA considered the adult population of the United States to be the target population for the estimate of health benefits. Although changes in dietary intake and biological factors in children may affect their later risk for CHD as adults, those changes, if present, have not been quantified and are beyond the scope of the health benefits assessment for this proposed rule. If reducing the *trans* fat intake of children does lead to later reduction in the risk of CHD, then the analysis of the proposed rule will underestimate the health benefits of decreasing *trans* fat intake.

1. Changes in *Trans* Fat Intakes

Three aspects of the estimated changes in *trans* fat intake will be discussed, as follows:

a. Baseline *trans* fat intake,

b. Quantitative changes in *trans* fat intake, and

c. Qualitative changes in the type of macronutrient substituted for *trans* fat.

a. *Baseline trans* fat intake. As reviewed in section IV.B.2.c of this document, most of the current estimates of *trans* fat intake have been based on either food disappearance data or food frequency questionnaires (Ref. 3 and 70). Because information on *trans* fat content of foods is limited, there have been few estimates of *trans* fat intake based on dietary surveys using food records or recalls. Allison et al. (Ref. 26) estimated *trans* fat intake by linking a special 1995 USDA data base on *trans* fat content of foods with USDA's CSFII, 1989 through 1991.

To estimate baseline *trans* fat intake, FDA first used the special 1995 USDA data base to estimate the *trans* fat content of food groups defined by Standard Industrial Classification (SIC)

Codes (Ref. 73). As described in section VI.D.1 of this document, this estimate was limited to foods with *trans* fat from partially hydrogenated fats and oils. Next, FDA linked the *trans* fat content of SIC Code food groups with mean intake of food groups in USDA's CSFII 1994 through 1996. For adults, age 20 and older, mean *trans* fat intake was estimated at 7.62 g/day for men and 5.54 g/day for women (Ref. 73). The estimated mean energy intake was 2,455 kcal/day for men and 1,646 kcal/day for women (Ref. 79). Therefore, *trans* fats provide approximately 2.79 percent of energy for men and 3.03 percent of energy for women (using the general conversion factor in § 101.9(c)(1)(i)(C), 1 g fat = 9 kcal). Because estimates of baseline *trans* fat intake as a percent of energy are very similar for men and women, these data were combined into a single estimate by a simple average, 2.91 percent of energy.

FDA's estimate of baseline *trans* fat intake used in this analysis is within the range of previous estimates in the literature, summarized in section IV.B.2.c of this document. The estimates of both FDA and Allison et al. (Ref. 26) are based on CSFII surveys and the special USDA *trans* fat data base. Allison et al. (Ref. 26) reported mean *trans* fat intake of 5.3 g/day (2.6 percent of energy). There are several differences in the method of estimation that would likely account for the differences in the two estimates. FDA's estimate used CSFII 1994–1996, was based on mean intake of food groups, and included men and women age 20 and older. The estimate of Allison et al. used CSFII 1989 through 1991, was based on specific foods eaten by each individual, and included males and females age three and older.

As discussed in section VI.D.5 of this document, FDA estimates that about 30 percent of the margarine products currently on the market have already been reformulated to remove *trans* fat. FDA also estimates that, in the short term, the rest of the margarine on the market would be reformulated in response to a final rule based on this proposed rule. Additionally, FDA estimates that some proportion of baked goods products would eventually be reformulated to remove *trans* fat. Table 1 of this document shows the average *trans* fat intake from the food groups likely to be affected by reformulation. The *trans* fat intake from margarine products in Table 1 of this

document represents the intake from the remaining 70 percent of margarine products currently on the market that is estimated to contain *trans* fat. As shown in Table 1 of this document, of the 2.91 percent of energy from *trans* fat intake, 0.39 percent is from the margarine food group, 0.67 percent from breads and cake products, and 0.98 percent from cookies and crackers.

TABLE 1.—CURRENT AVERAGE *trans* Fat Intake by Adults From Food Groups[1]

Food Group	SIC Code[2]	Current Average *Trans* Fat Intake				
		Men[3]		Women[4]		Average
		gm/day	% of energy	gm/day	% of energy	% of energy
Margarine	2079	1.02	0.37%	0.75	0.41%	0.39
Bread/Cake/etc.	2051	1.77	0.65%	1.28	0.70%	0.67
Cookies/Crackers	2052	2.48	0.91%	1.92	1.05%	0.98
All Other		2.35	0.86%	1.59	0.87%	0.87
Total		7.62	2.79%	5.54	3.03%	2.91

[1] Data for adults, age 20 and older (see section VI.C.1 of this document). Conversion factor: 1 gram *trans* fat intake equals 9 kcal.
[2] SIC, Standard Industrial Classification.
[3] Mean energy (caloric) intake: 2,455 kcal per day for men.
[4] Mean energy (caloric) intake: 1,646 kcal per day for women.

b. *Quantitative changes in trans fat intake: Four scenarios.* FDA developed several scenarios to demonstrate potential quantitative changes in *trans* fat intake based on a range of possible producer and consumer responses to labeling *trans* fat content. Although FDA has characterized these changes as "producer" and "consumer" responses, all responses to the proposed rule are based on the interactions in the food market between changes in producer cost and changes in consumer demand. In the analysis done for the 21 implementing rules for the 1990 amendments, FDA acknowledged that there would be both costs and benefits arising from the reformulation of products likely to occur as a result of the rules. FDA chose not to quantify those costs and benefits in that analysis (in contrast to the analysis of this proposed rule) because of the uncertainty associated with estimating producer reactions to complex label changes.

For the rule now being proposed, the reactions of producers to the proposed rule can be estimated quantitatively. Including the reactions of producers, however, makes it difficult to compare the effects of the proposed rule with the effects of the 1990 amendments, which may be considered a standard of comparison for major labeling rules. In section VI.E of this document, FDA calculates the benefits and costs of this proposed rule with methods similar to those used for the rules implementing the 1990 amendments, which allows the effects of the two rules to

be compared. The characteristics of each scenario used to estimate the effects of the proposed rule are summarized in Table 2 of this document.

i. *Scenario 1: Maximum response.* In Scenario 1, the maximum response, a combination of reformulation and consumer response eliminates all *trans* fat. As shown in Table 2 of this document, in Scenario 1, 100 percent of *trans* fat would be removed from the diet, decreasing the intake of *trans* fat by 2.91 percent of energy. Because of the magnitude of producer and consumer response, FDA considers Scenario 1 the least likely of the four scenarios, but has used it to illustrate the upper bound of possible decreases in *trans* fat intake.

ii. *Scenario 2: Some reformulation and some consumers change their behavior.* In Scenario 2, 100 percent of margarine, 3 percent of bread and cake, and 15 percent of cookies and crackers would be reformulated to remove *trans* fat. FDA assumed that the percentage *amounts* of bread, cake, cookies, and crackers reformulated would be about double the percentage *number* of products reformulated (see Table 17 later in this document). The percentage change in amounts exceeded the percentage change in number of products because FDA expected that the products to be reformulated will all be produced by large firms. Indeed, FDA expects that all large firms whose products contained claims that would be lost will reformulate. The agency assumed that these products account for above-average shares of bread, cake, cookies, and crackers containing *trans* fat. FDA requests comments on the assumptions that 3 percent of bread and cake and 15 percent of cookies and crackers will be reformulated by 7 years after the compliance period (scenario 2). Given the mean *trans* fat intake shown in Table 1 of this document, these reformulations would decrease *trans* fat intake by 0.56 percent of energy ((1 x 0.0039) + (0.03 x 0.0067) + (0.15 x 0.0098) = 0.0056).

Because of the sizable cost of reformulation and the limited consumer appeal that bread and cake products, cookies, and crackers with claims have had thus far, FDA assumes that only a small percentage decrease in *trans* fat intake from reformulation of the products in these categories is a likely result of the proposed rule. If producers believe that consumers will respond more

negatively to the information on *trans* fat than they have responded thus far to the information on saturated fat, then the actual number of products reformulated will be greater. If that happens, the actual benefits of the rule will be greater than those estimated here; the costs will increase only proportionally, so the net benefits of the rule would be greater than estimated in this scenario.

In this scenario, not all consumers respond to the labeling changes by eliminating *trans* fat in the other categories of their diets. Previous research showed that approximately 45 percent of consumers are aware of diet-health links, and read and understand nutrition labels (Refs. 68 and 74). In Scenario 2, therefore, FDA assumed that 45 percent of consumers would eliminate some *trans* fat from their diets.

Those consumers who read and understand nutrition labels are expected, on average, to make choices among existing products that result in only small changes in *trans* fat intake. In analyzing the anticipated health benefits of the regulations implementing the 1990 amendments (56 FR 60856 at 60870), FDA estimated consumer changes in consumption behavior using the results of previous research, including a study of grocery store shelf labeling (Refs. 68 and 74). In that analysis of changes in market share, consumer response to shelf labeling of 49 product categories resulted in an approximately 1 percent overall decrease in intake of total fat and saturated fat. FDA therefore used a 1 percent overall decrease in *trans* fat intake as an estimate of consumer response to this proposed labeling change. An overall 1 percent decrease in *trans* fat intake would be obtained if the 45 percent of consumers who use food labels to make purchase decisions changed their consumption by 2.2 percent ($0.01 \div 0.45 = 0.022$). The 55 percent of consumers who do not pay attention to food labels would decrease *trans* fat intake by 0.56 percent of energy because of reformulation only. The remaining 45 percent of consumers would decrease *trans* fat intake by 0.61 percent of energy, 0.56 percent due to reformulation plus 0.05 percent due to elimination of 2.2 percent of the *trans* fat from foods not reformulated ($0.022 \times (0.0291 - 0.0056) = 0.0005$). The total change in *trans* fat intake as a percent of energy would be 0.58 percent ($(0.55 \times 0.0056) + (0.45 \times 0.0061) = 0.0058$).

The 1-percent decrease in *trans* fat intake that FDA assumed for consumers may understate the direct consumer response. The agency took the 1-percent decrease from studies undertaken in support of the analysis of the rules implementing the 1990 amendments. The 1990 amendments required labeling changes for all FDA-regulated foods; the supporting studies estimated the change in fat and saturated fat as part of the outcome of changes in the overall diet in response to the new label. Rather than affecting all FDA-regulated foods, however, the proposed labeling of *trans* fat will mainly affect foods containing 0.5 g or more of *trans* fat per serving, which are predominantly products containing partially hydrogenated fats and oils, as described in section VI.D.1 of this document (Ref. 73). The narrower scope of the proposed labeling may, by emphasizing a single substance, generate a larger direct consumer response.

In the shelf-labeling study, the reported change in market share ranged from 1 percent to 40 percent in 18 product categories and no significant change was reported in the remaining 31 categories (Refs. 72 and 74). The predicted consumer response in the specific product categories affected by *trans* fat labeling is, therefore, uncertain. In previous research, it was noted that different circumstances make it difficult to generalize consumer response from one food labeling or health claim situation to another (Ref. 74). In the absence of specific research on the reaction of consumers to *trans* fat labeling (Ref. 81), FDA used the estimate of a 1-percent decrease in intake, as used previously for the rules implementing the 1990 amendments.

iii *Scenario 3: Less reformulation and some consumers change their behavior.* In Scenario 3, 100 percent of margarine, 1.5 percent of bread and cake, and 7.5 percent of cookies and crackers would be reformulated—half the reformulation of baked products of Scenario 2. Given the mean *trans* fat intake shown in Table 1 of this document, this would decrease *trans* fat intake by 0.48 percent of energy ((1 x 0.0039) + (0.015 x 0.0067) + (0.075 x 0.0098) = 0.0048). Scenario 3 assumes the same direct consumer response as in Scenario 2. Under scenario 3, 55 percent of consumers decrease *trans* fat intake by 0.48 percent of energy due to reformulation. The remaining 45 percent of consumers decrease *trans* fat intake by 0.53 percent of energy, 0.48 percent due

to reformulation plus 0.05 percent due to elimination of 2.2 percent of the *trans* fat from foods not reformulated (0.022 x (0.0291 - 0.0048) = 0.0005). The total change in *trans* fat intake as a percent of energy would be 0.50 percent ((0.55 x 0.0048) + (0.45 x 0.0053) = 0.005).

iv. *Scenario 4: Least reformulation and some consumers change their behavior.* Scenario 4 assumes no reformulation of bread and cake products, but continues to assume reformulation of margarine. Scenario 4 also assumes the same direct consumer response as in Scenarios 2 and 3. Under this scenario, 55 percent of consumers would decrease *trans* fat intake by 0.39 percent of energy due to margarine reformulation only. The remaining 45 percent of consumers decrease *trans* fat intake by 0.45 percent of energy, 0.39 percent due to reformulation plus 0.06 percent due to elimination of 2.2 percent of the *trans* fat from foods not reformulated (0.022 x (0.0291 - 0.0039) = 0.0006). The total change in *trans* fat intake as a percent of energy would be 0.42 percent ((0.55 x 0.0039) + (0.45 x 0.0045) = 0.0042).

As summarized in Table 2 of this document, Scenarios 2 through 4 predict three levels of product reformulation together with an estimate of consumer behavior. FDA considers Scenarios 2 through 4 to be more likely than Scenario 1, and has used them as the primary basis for estimation of health benefits. In addition to representing outcomes with different likelihoods, the three scenarios represent the effects of the proposed rule after different periods of time: 3 years after the effective date for Scenario 4, 8 years after the effective date for Scenario 3, and 10 years after the effective date for Scenario 2. The time period for the effects of each of the three scenarios includes the time for reformulation and the 3 years that pass before changes in diet affect the risk of CHD.

TABLE 2.— PREDICTED CHANGES DUE TO *trans* FAT LABELING[1]

Characteristics of Each Scenario	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Description	Maximum combined producer and consumer response	Some reformulation and a proportion of consumers have partial behavior change	Less reformulation and a proportion of consumers have partial behavior change	Least reformulation and a proportion of consumers have partial behavior change
Margarine Category		100% Reformulated	100% Reformulated	100% Reformulated
Bread/Rolls Category		3% Reformulated	1.5% Reformulated	Not Reformulated
Cookies/Pastries Category		15% Reformulated	7.5% Reformulated	Not Reformulated

TABLE 2.— PREDICTED CHANGES DUE TO *trans* FAT LABELING[1]—Continued

Characteristics of Each Scenario	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Foods Not Reformulated		45% of consumers pay attention to labels and eliminate 2.2% of *trans* fats	45% of consumers pay attention to labels and eliminate 2.2% of *trans* fats	45% of consumers pay attention to labels and eliminate 2.2% of *trans* fats
Decrease in Average *Trans* Fat Intake (% of energy)	2.91	0.58	0.50	0.42
Change in Coronary Heart Disease Risk				
Method 1, LDL	- 4.28%	- 0.86%	- 0.73%	- 0.61%
Method 2, LDL and HDL	- 8.36%	- 1.67%	- 1.43%	- 1.20%

Time Periods for the Effects of Scenarios[2]

Time after effective date	Scenario 1	Scenario 2	Scenario 3	Scenario 4
3 years	Same effects as scenario 4	Same effects as scenario 4	Same effects as scenario 4	Full effect for scenario 4
8 years	Same effects as scenario 3	Same effects as scenario 3	Full effect for scenario 3	Full effect for scenario 4
10 years	Full effect for scenario 2	Full effect for scenario 2	Full effect for scenario 3	Full effect for scenario 4
Hypothetical future time (more than 10 years)	Full effect for scenario 1	Full effect for scenario 2	Full effect for scenario 3	Full effect for scenario 4

[1] It is assumed in this table that a given percent of energy from *trans* fats is replaced by the same percent of energy from *cis*-monounsaturated fats, keeping total energy intake constant. The effect of substituting other macronutrients for *trans* fats is shown in Table 3 of this document.

[2] The calculations used to estimate the changes in risk (listed in the second part of the table) are explained below. For the calculations of risk using the LDL model, see section VI.C.2.a of this document. For the calculations of risk using the LDL and HDL model, see section VI.C.2.b of this document.

c. *Qualitative changes, substituting different macronutrients for trans* fats. Although quantitative decreases in *trans* fat intake were estimated for the four scenarios in the preceding section, the actual substitutions manufacturers and consumers will make as a result of the labeling change are uncertain. The four scenarios assume that the margarine food group will be reformulated, and scenarios 1 through 3 assume that a proportion of products in the breads, cookies, and crackers food groups will be reformulated to eliminate *trans* fat.

In choosing among reformulated products, manufacturers and consumers might use products with saturated fat, *cis*-monounsaturated fat, or *cis*-polyunsaturated fat as substitutes for the *trans* fat removed by reformulation. Some industry specialists estimate that current food technology will require the incorporation of about 0.5 g saturated fat for every 1 g *trans* fat removed from a food product by reformulation (Ref. 73). However, if consumers choose a very low fat (and low calorie) replacement product, they will obtain almost no fat in substitution for *trans* fat. They might then increase their intake of carbohydrate or other fat to replace the calories from the replacement product. Similarly, in the four scenarios FDA assumes that at least some consumers

will eliminate at least some *trans* fat from their diets because of the labeling change. They will then obtain some combination of carbohydrate or other fat in the foods they choose in place of *trans* fat-containing foods.

In the scientific literature, *cis*-monounsaturated fat is often used as a reference point in describing effects of *trans* fat intake. Because there are no available data to predict which macronutrients might, in fact, replace *trans* fat, it is important to consider how the substitution of carbohydrate or of other types of fat would influence the CHD risk estimates. Therefore, in estimating the potential decrease in heart disease risk due to *trans* fat labeling, FDA first estimated the effect on CHD risk by assuming that the *trans* fat eliminated from the diet was replaced with *cis*-monounsaturated fat while holding energy (calories) constant. Next, FDA considered the effect on CHD risk of replacing a given percent of energy from *trans* fat with the same percent of energy from a combination of 50 percent *cis*-monounsaturated fat, plus either 50 percent saturated fat, 50 percent polyunsaturated fat, or 50 percent carbohydrate. The effects of different substitutions for *trans* fats are shown in Table 1 of this document. In valuing health benefits, FDA assumed likely substitutions of ingredients for the *trans* fat now used in different products (see section VI.C.3 of this document).

2. Changes in Health States Due to Changes in *Trans* Fat Intake

FDA used two methods to estimate the potential decrease in CHD likely to result from decreased intake of *trans* fat in response to the labeling change.

a. Method 1. Decrease in CHD risk due to decreased serum concentrations of LDL–C.

b. Method 2. Decrease in CHD risk due to decreased serum concentrations of LDL–C and increased serum concentrations of HDL–C. FDA also reviewed the association of CHD risk with *trans* fat intake found in large prospective observational cohort studies.

In the following sections, FDA summarizes the estimated decrease in CHD using each method.

a. *Method 1: Changes in LDL–C.* As noted in section IV.B.2 of this document, the NCEP Expert Panel (Ref. 5) found increases in serum LDL–C to be a major risk factor for CHD. In

keeping with the recommendations of the NCEP Expert Panel, FDA used changes in serum LDL–C as the primary criterion to evaluate the effects of *trans* fat intake on CHD risk in Method 1.

As discussed in section IV.B.2.b of this document, clinical trials of *trans* fat feeding have the advantage that they provide evidence for a cause and effect relationship between a given level of *trans* fat intake and the observed changes in physiologic measures such as LDL–C. However, a single feeding trial usually involves just one or a few test diets in comparison with a reference diet (called a ''basal'' diet) and typically provides information on only one (or occasionally two or more) levels of *trans* fat intake. When summarizing or comparing the results of various feeding trials, the different levels of *trans* fat intake and different basal diets across studies make the comparisons necessary for this benefits analysis difficult.

To overcome these difficulties, FDA used the regression equations of Katan et al. (Ref. 62) and Zock et al. (Ref. 69) in Method 1 to estimate the effect of *trans* fat intake on LDL–C. These authors considered the results of five feeding trials (and six levels of *trans* fat intake), summarizing the CHD risk results as a function of the level of *trans* fat intake. Small differences in the basal diets in each study were accounted for by correction factors based on the regression equations of Mensink and Katan (Ref. 65). Compared with the results of a single feeding trial, the coefficients from the regression equations had three advantages: (1) They were based on data from a larger number of subjects, (2) they could be generalized over a range of *trans* fat intake, and (3) they were adjusted to a common basal diet.

The regression equation of Katan et al. (Ref. 62) and Zock et al. (Ref. 69) was based on the following studies that were reviewed in section IV.B.2 of this document: Judd et al. 1994, Mensink and Katan 1990, Lichtenstein et al. 1993, Nestel et al. 1992, Zock and Katan 1992 (Refs. 7, 8, and 11 through 13). The regression equation showed that each additional percent of energy from *trans* fat was predicted to increase LDL–C by 1.5 mg/deciliter (dL) (0.040 millimol/liter) ($R^2 = 0.86$, $p = 0.0028$) when substituted for the same percent of energy from *cis*-monounsaturated fat, holding total energy intake constant.

Previous research has shown that each 1-percent reduction in total serum cholesterol is associated with a decrease in CHD risk by a factor of 2 percent (Ref. 5). To quantify the relationship between changes in LDL–C and CHD risk, Gordon and coworkers carried out a standardized reanalysis of CHD incidence in four large prospective studies in the United States (Refs. 59 through 61). The results of Gordon and coworkers showed that each increment of 1 mg/dL in LDL–C (0.026 millimol/liter) was predicted to increase CHD risk by a factor of 0.6 percent to 0.8 percent (Refs. 59 through 61). FDA used the midpoint of this range, a 0.7 percent increase in risk per 1 mg/dL LDL–C increment, in the present analysis (throughout this analysis, a percent change in CHD risk means that change as a factor of existing risk). Because Gordon and coworkers expressed the change in LDL–C in mg/dL rather than as a percent of mean LDL–C concentration, the information was directly applicable to the changes in LDL–C in the intervention (feeding) studies.

Because an individual's serum lipid concentrations vary over time, a single measurement of serum lipid levels may underestimate the magnitude of the association between serum lipids and CHD risk (Refs. 5, 57, and 64). Single measurements include random variation (or error) that would be removed if repeated measurements of serum lipids were made and the results for each individual were averaged. The presence of the additional random variation can statistically mask the actual relationship between serum lipids and CHD, causing an underestimate of the magnitude of the association. This apparent weakening of the observed association relative to the true association is called regression dilution bias (Refs. 57 and 64). In an analysis of data from the British United Providence Association, statistical removal of the regression dilution bias increased the association between serum cholesterol and CHD by a factor of 1.4 (Ref. 64). In this analysis, therefore, FDA increased the strength of the relationship between LDL–C and CHD risk by a factor of 1.4 to correct for regression dilution bias. Using these relationships, the change in CHD risk due to *trans* fat labeling can be predicted under the four consumer response scenarios.

Given the mean decrease in *trans* fat intake of 2.91 percent of energy in Scenario 1, LDL–C is predicted to decrease by 4.37 mg/dL, resulting in a decrease in CHD risk of 3.06 percent, or 4.28 percent (1.4 x 3.06 percent) after adjustment. Because the relationships in Method 1 are linear, the decreased *trans* fat intake of the consumers who do and those who do not use labels to make purchase decisions can be combined into a single estimate of net decrease in *trans* fat intake. For Scenario 2, the net decrease in *trans* fat intake is 0.58 percent of energy, predicting a 0.87 mg/dL decrease in LDL–C, a 0.61 percent decrease in risk of CHD, and a 0.86 percent (1.4 x 0.61 percent) adjusted decrease in risk of CHD. In Scenario 3, the net decrease in *trans* fat intake is 0.50 percent, giving a 0.75 mg/dL decrease in LDL–C, a 0.52 percent decrease in CHD, and a 0.73 percent (1.4 x 0.52 percent) adjusted decrease in risk of CHD. In Scenario 4, mean *trans* fat intake decreases by 0.42 percent of energy, resulting in a 0.63 mg/dL decrease in LDL–C, a 0.44 percent decrease in CHD risk, and a 0.61 percent (1.4 x 0.44 percent) adjusted decrease in risk of CHD. The adjusted decreases in risk for the four scenarios are summarized in Table 2 of this document.

Because the regression equations of Katan et al. (Ref. 62) and Zock et al. (Ref. 69) represent the result of a mathematical procedure, rather than the results of individual experiments, it is important to consider how the decrease in risk calculated compares with individual studies or with other summaries of studies. FDA compared these results with predictions based on the feeding trials of Mensink and Katan (Ref. 7) and Judd et al. (Ref. 12) and on the summary of Kris-Etherton et al. (Ref. 63). FDA found that the decreased CHD risk predicted in this analysis was within the range predicted using estimates derived from individual feeding trials and from other summaries of research.

In the estimates using Method 1, FDA assumed that energy as *trans* fat will be replaced by energy as *cis*-monounsaturated fat. To account for the substitution of different macronutrients for *trans* fat, FDA compared these estimates with the effect on CHD risk of replacing a given percent of energy from *trans* fat with the same percent of energy from a combination of 50 percent

cis-monounsaturated fat plus either 50 percent saturated fat, 50 percent polyunsaturated fat, or 50 percent carbohydrate. FDA examined this effect by considering the effect of carbohydrate and other fat on LDL–C. Mensink and Katan (Ref. 65) used regression equations to summarize the results of 27 clinical feeding trials on serum lipids. When substituted for 1 percent of energy from monounsaturated fat, polyunsaturated fat lowered LDL–C slightly (-0.31 mg/dL), carbohydrate raised LDL–C slightly (0.24 mg/dL), and saturated fat raised LDL–C a similar amount (1.52 mg/dL) to that found for *trans* fat (1.50 mg/dL).

Given these effects of various substitutions on LDL–C, the changes in CHD risk can be estimated. As examples, the results for Scenarios 2 and 4 are summarized in Table 3 of this document. The replacement of 0.58 percent of energy from *trans* fat (Scenario 2) with half *cis*-monounsaturated fat and half other fat or carbohydrate gives a decreased adjusted risk of 0.42 percent for saturated fat, 0.95 percent for polyunsaturated fat, and 0.79 percent for carbohydrate. These risks compare with 0.86 percent for replacement with only *cis*-monounsaturated fat under Scenario 2. Under Scenario 4 (replacement of 0.42 percent of energy from *trans* fat), the corresponding decreases in risk are 0.30 percent, 0.68 percent, and 0.56 percent for replacement with half *cis*-monounsaturated fat and, respectively, either half saturated fat, half polyunsaturated fat, or half carbohydrate. These risks compare with 0.61 percent for replacement with only *cis*-monounsaturated fat. Under Method 1, then, the decrease in CHD risk is smallest when saturated fat replaces some of the *trans* fat that is removed.

b. *Method 2: Changes in HDL–C and LDL–C.* As noted in the discussion on intervention (feeding) studies in section IV.B.2.a of this document and in Appendix A, Table 1 of this document, *trans* fat intake appears to affect not only LDL–C, but also other serum lipids, including HDL–C, as well. A Consensus Statement on triglyceride, high-density lipoprotein, and coronary heart disease reported ''considerable support for a causal relationship'' between HDL–C and CHD (Ref. 71). The NCEP Expert Panel (Ref. 5) considered LDL–C to be the primary lipid risk factor for CHD. The Expert Panel also noted, however, the role of HDL–C as a ''significant'' lipid risk

factor for CHD. The Expert Panel stated, ''Even though there are no data from clinical trials designed specifically to show that raising HDL–C levels will reduce the risk for CHD, the strong epidemiological association between low HDL–C and CHD justifies considering HDL–C in risk assessment.'' The NCEP Expert Panel (Ref. 5) found that ''the strength and independence of this association warrants calling low HDL–C * * * a [negative] risk factor for assessing the risk status of individual patients and for influencing the vigor of treatment directed at high levels of LDL–C.''

Although FDA believes that justification for this proposed rule is primarily through the effect of *trans* fat intake on LDL–C, *trans* fat intake may also be associated with CHD through an effect on HDL–C. Therefore, with this noted qualification, FDA used changes in both HDL–C and LDL–C as a second method to quantify the effects of *trans* fat intake on CHD risk.

The effect of *trans* fat intake on HDL–C was also quantified by Katan et al. and Zock et al. (Ref. 62 and 69). The regression equation showed that each additional percent of energy from *trans* fat was predicted to decrease HDL–C by 0.4 mg/dL (0.013 millimol/liter) ($R^2 = 0.88$, $p = 0.0019$) when substituted for the same percent of energy from *cis*-monounsaturated fat, holding total energy intake constant. According to the analyses of Gordon and coworkers (Refs. 59 through 61), each 1 mg/dL (0.026 millimol/liter) increment in HDL–C was predicted to decrease CHD risk by 2 percent to 3 percent. For the purpose of this analysis, FDA chose the midpoint, a 2.5 percent decrease in risk per 1 mg/dL HDL–C increment. As described earlier, the strength of this relationship should be increased by a factor of 1.4 to account for regression dilution (Ref. 64).

For Scenario 1, the mean 2.91 percent of energy decrease in *trans* fat intake is predicted to increase HDL–C by 1.16 mg/dL, decreasing CHD risk by 2.91 percent or by 4.08 percent (1.4 x 2.91 percent) adjusted. The combined effect of the change in CHD risk due to changes in HDL–C and LDL–C predicts an 8.36 percent decrease in CHD risk in Scenario 1 (4.28 percent decreased risk from lowering LDL–C plus 4.08 percent decreased risk from raising HDL–C). Applying the same procedures to the increase in HDL–C in the other scenarios would result in decreasing CHD

risk by 0.82 percent, 0.70 percent, and 0.58 percent (adjusted) for Scenarios 2 through 4. The combined effect of raising HDL–C and lowering LDL–C, summarized in Table 2 of this document, would result in decreasing CHD risk by 1.67 percent, 1.43 percent, and 1.20 percent for Scenarios 2 through 4. As found for Method 1, the decreased CHD risk predicted for Method 2 using the regression equations of Katan et al. and Zock et al. (Refs. 62 and 69) was within the range predicted using estimates derived from individual feeding trials and from summaries of research.

In the estimates using Method 2, which estimated changes in both HDL–C and LDL–C, FDA assumed that *trans* fat was replaced by the same percent of energy as *cis*-monounsaturated fat. To account for the substitution of different macronutrients, FDA compared the Method 2 estimates with the effect on CHD risk of replacing a given percent of energy from *trans* fat with the same percent of energy from a combination of half *cis*-monounsaturated fat and half either saturated fat, polyunsaturated fat, or carbohydrate. FDA examined these effects by considering the effects of carbohydrate and other fat on both LDL–C (summarized previously for Method 1) and HDL–C. The regression equations of Mensink and Katan (Ref. 65) predicted that when substituted for one percent of energy from monounsaturated fat, polyunsaturated fat lowered HDL–C slightly (0.06 mg/dL), saturated fat raised HDL–C slightly (0.13 mg/dL), and carbohydrate lowered HDL–C by a similar amount (0.34 mg/dL) to that found for *trans* fat (0.40 mg/dL).

Using Method 2, which includes the effects on both HDL–C and LDL–C, the replacement of 0.58 percent of energy from *trans* fat (Scenario 2) with half *cis*-monounsaturated fat and half other fat or carbohydrate gives a decreased adjusted risk of 1.37 percent for saturated fat, 1.70 percent for polyunsaturated fat, and 1.26 percent for carbohydrate (Table 3 of this document). These changes compare with the 1.67 percent decreased CHD risk calculated for replacement with only *cis*-monounsaturated fat under Scenario 2. Using Method 2 and Scenario 4, the corresponding decreases in risk are 0.98 percent for saturated fat, 1.22 percent for polyunsaturated fat, and 0.90 percent for carbohydrate, compared with 1.20 percent adjusted decrease in CHD risk for replacement with only *cis*-monounsaturated fat. Under Method 2, therefore, the decrease in CHD

risk is not as large when saturated fat or carbohydrate is used to replace some of the *trans* fat that is removed.

TABLE 3.—PREDICTED CHANGES IN CORONARY HEART DISEASE (CHD) RISK DUE TO *trans* FAT LABELING, ACCORDING TO SUBSTITUTION FOR *trans* FATS

	Scenario 2		Scenario 4	
Description	Some reformulation and a proportion of consumers have partial behavior change		Least reformulation and a proportion of consumers have partial behavior change	
Decrease in average *trans* fat intake (% of energy)	0.58		0.42	
Substitution for *trans* fats	Change in CHD Risk: Method 1, LDL–C	Change in CHD Risk: Method 2, LDL–C and HDL–C	Change in CHD Risk: Method 1, LDL–C	Change in CHD Risk: Method 2, LDL–C and HDL–C
cis-monounsaturated fats	- 0.86%	- 1.67%	- 0.61%	- 1.20%
Half saturated and half *cis*-monounsaturated fats	- 0.42%	- 1.37%	- 0.30%	- 0.98%
Half *cis*-polyunsaturated and half *cis*-monounsaturated fats	- 0.95%	- 1.70%	- 0.68%	- 1.22%
Half carbohydrate and half *cis*-monounsaturated fats	- 0.79%	-1.26%	- 0.56%	- 0.90%

In June 1999, Ascherio et al. published an updated regression equation estimating the effect of *trans* fat intake on serum lipids (Ref. 83). The equation of Ascherio et al. incorporated the results of 8 feeding trials at 12 levels of *trans* fat intake, including 4 levels of *trans* fat intake from the newly-published feeding trial of Lichtenstein et al. (Ref. 82). In Method 1 and Method 2 of this document, FDA estimated the effect of *trans* fat intake on serum lipids using the 1995 regression equations of Katan et al. (Ref. 62) and Zock et al. (Ref. 69). The 1999 equation of Ascherio et al. (Ref. 83) estimated the effect of *trans* fat intake on the ratio of LDL–C to HDL–C (LDL/HDL ratio), and not on the separate lipid concentrations of LDL–C and HDL–C. As discussed in greater detail in sections IV.B.2 and VI.C.2 of this document, FDA's primary rationale for this proposed rule is the effect of *trans* fat on LDL–C. Therefore, FDA estimated the effects of *trans* fat on LDL–C and HDL–C separately, and FDA did not use the 1999 equation of Ascherio et al. However, FDA notes that the effect of *trans* fat intake on serum lipid ratios estimated by the 1999 equation of Ascherio et al. (Ref. 83) is very similar to the effect on serum lipid ratios estimated by the 1995 equation of Willett and Ascherio (Ref. 84). Moreover, the 1995 equation of Willett and Ascherio incorporated the results of the same five feeding trials at six levels of *trans* fat intake as did the equations of Katan et al. (Ref. 62) and Zock et al. (Ref 69) that the

agency used in Method 1 and Method 2 of this document. Therefore, FDA concludes that the decreased CHD risk predicted by Method 1 and Method 2 of this document would not be appreciably changed even if a regression equation were available to it that predicted LDL–C and HDL–C separately, and incorporated the most recently published feeding trials.

c. *Estimates from large prospective studies.* As noted in section IV.B.2.b of this document, FDA reviewed the results from observational epidemiological studies of *trans* fat intake and risk of CHD. Because such studies can provide evidence of an association between a risk factor and disease, but cannot establish direct cause and effect, FDA considered the evidence from observational epidemiological studies as indirect evidence for a relationship.

Among the observational studies reviewed, FDA is aware of four large prospective studies reporting association between *trans* fat intake and CHD risk (Refs. 19 through 21 and 38). These studies suggest benefits that are several fold higher than even the high estimate of benefits presented previously in this analysis (i.e., benefits estimated for Method 2). FDA is asking for comments on the use of these studies in estimating benefits.

In these studies, the dietary intake and the health status of the prospective cohorts were followed over time. An advantage of prospective studies is that knowledge of a disease does not influence the reported dietary intake (from questionnaires) (Ref. 66). However, in prospective studies (as in other observational epidemiology), there is error included in individuals' self-reported dietary intake and in the calculation of *trans* fat intake from foods reported eaten.

Additionally, statistical techniques are used to adjust for other dietary components and other characteristics of the subjects that may potentially confound the relationship between *trans* fat intake and CHD. If a direct cause and effect is present, the size of the effect may be over- or underestimated if there is bias due to errors in measurement of the other dietary components or other confounding factors. The presence of unknown or unmeasured confounding factors is another potential source of bias. The prospective studies have nevertheless consistently reported a greater

risk of CHD attributable to *trans* fat intake than would be accounted for by changes in LDL–C and HDL–C alone.

Prospective studies typically report the association of a risk factor with a disease outcome in terms of ''relative risk.'' RR indicates the degree to which the presence of the risk factor increases the chance of the health outcome. For example, an RR of 1.5 means that with the risk factor present there is a 50 percent greater chance of having the disease than if the risk factor was not present (holding all other factors constant and assuming a cause and effect relationship for the risk factor and the disease).

In the study of Hu et al. (Ref. 38), women completed diet questionnaires four separate times during a 14-year followup. The RR for CHD was reported to be 1.93 per 2 percent of energy intake from *trans* fat, with a 95 percent confidence interval ranging from 1.43 to 2.61. These numbers indicate that for every 2 percent of energy (calories) from *trans* fat, there would be an increased risk of CHD of 93 percent (compared with the same amount of energy from carbohydrates). When only the initial diet questionnaire was used in the analysis (instead of all four questionnaires), greater measurement error was expected, and the RR for CHD was reduced to 1.62 per 2 percent of energy from *trans* fat (95 percent confidence interval from 1.23 to 2.13). This study can be compared to the study of men by Ascherio et al. (Ref. 19), using a single diet questionnaire, which reported a RR of 1.36 per 2 percent of energy from *trans* fat (95 percent confidence interval from 1.03 to 1.81).

Three of the prospective studies (Refs. 20, 21, and 38) reported the CHD risk for the subjects in the top 20 percent of energy intake from *trans* fat compared with those in the lowest 20 percent of intake. Again, the reported RR's were greater than 1.0 with overlapping confidence intervals. In addition, a report from the Framingham Heart Study found the RR for CHD in men was 1.12 per teaspoon margarine intake, with 95 percent confidence interval from 1.05 to 1.20 (Ref. 58). This result corresponds to an RR of 2.05 per 2 percent of energy from *trans* fat (95 percent confidence interval from 1.36 to 3.17), which is very similar to the results of Hu et al. (assuming

that a tablespoon (3 teaspoons) of margarine contains 11 g of fat and that 25 percent of the fat in margarine is *trans* fat).

As a further check, the RR reported by Hu et al. (Ref. 38) for saturated fat may be compared to other prospective studies, such as the analysis from the Western Electric Study by Shekelle et al. (Ref. 67). The coefficient reported by Shekelle et al. corresponds to a RR of 1.17 per 5 percent of energy from saturated fat, the same as was reported by Hu et al. (Ref. 38).

When used to predict the health benefits of replacing *trans* fat with other types of fats or carbohydrates, the Hu et al. (Ref. 38) paper gives decreases in CHD much larger than those predicted using only changes in LDL–C and HDL–C. For example, Hu et al. reported that substitution of monounsaturated fat for *trans* fat at 2 percent of energy would decrease CHD risk by 52.4 percent (95 percent confidence interval of 37 percent to 64 percent).

Under Scenario 2, FDA calculated the estimated decrease in risk for CHD when monounsaturated fat is substituted for *trans* fat. In this scenario, *trans* fat intake decreases by 0.61 percent of energy for 45 percent of consumers and by 0.56 percent of energy for 55 percent of consumers, with a weighted average decrease of 0.58 percent. Using the relationships of Hu et al. (Ref. 38), the estimated weighted average decrease in CHD risk is 19.4 percent (95 percent confidence interval of 5.2 percent to 31.6 percent). This decrease is much larger than the decrease of 1.67 percent estimated for Method 2, which considered effects for both LDL–C and HDL–C. Even 5.2 percent, the lower limit of the 95 percent confidence interval, is three times higher than the LDL–C and HDL–C combined prediction of 1.67 percent.

Because of the possibilities of errors of measurement (particularly of dietary intake) or poorly measured or missing confounding variables, the RR's from these observational studies are imprecise. Although observational studies have limitations, they also have the advantage that they can measure directly (within a given study) an association between dietary intake and disease outcome. This association cannot be established from the short-term feeding trials. In such trials *trans* fat is fed to people for a few weeks, changes in serum lipids are measured, and it is assumed

that the CHD risk associated with *trans* fat intake occurs through the mechanism of changes in LDL–C and possibly HDL–C. In contrast, the observational studies measure actual CHD occurrence in a large group of people over a period of years, and describe all CHD risk associated with *trans* fat intake, regardless of the mechanism of action by which *trans* fat intake may be associated with CHD. The prospective studies therefore raise the possibility that there may be additional mechanisms by which *trans* fat contributes to CHD (such as increases in fasting triglycerides and increases in lipoprotein (a) (Ref. 62)), and that the actual benefits may be higher than estimated using Methods 1 and 2.

3. Value of Changes in Health

In the previous sections, FDA presented potential changes in food markets because of this proposed rule and described various ways of calculating the decreases in CHD that would result from those market changes. Uncertainties in these analyses include:

- The size of consumer substitutions among existing products;
- The amount of producer reformulation to avoid losing market shares;
- The types of ingredient substitutions producers will make to reduce the amount of *trans* fat in their products; and,
- The decrease in CHD that will result from decreased *trans* fat in the diet.

FDA estimated the benefits from the proposed rule for three scenarios and two methods. The three scenarios estimate plausible changes over time in the intake of *trans* fat. The short-term benefits are associated with the reformulation of margarine and direct consumer substitutions within the existing product mix (Scenario 4). FDA assumed that the most likely ingredient substitutions for *trans* fat in margarine would be 100 percent *cis*-monounsaturated fat, or a mixture of 50 percent *cis*-monounsaturated and 50 percent *cis*-polyunsaturated fat, or a mixture of 50 percent *cis*-monounsaturated and 50 percent saturated fat (Ref. 73). After 5 years additional benefits are associated with some reformulation of baked goods (the increase in benefits estimated for Scenario 3 over Scenario 4). Finally, after 2 more years additional baked goods reformulation leads to greater

benefits (the increase in benefits estimated for Scenario 2 over Scenario 3). FDA assumed that the most likely ingredient substitution for *trans* fat in baked goods would be a mixture of 50 percent *cis*-monounsaturated and 50 percent saturated fat.

The two methods give low and high estimates of the change in CHD risk brought about by changing intakes of *trans* fat. The low method (Method 1) assumes that the reduction in CHD risk associated with reduced *trans* fat intakes comes about through the reduction in LDL–C. The high method (Method 2) assumes that the reduction in CHD risk comes about through a combination of reducing LDL–C and increasing HDL–C.

The reduction in CHD is highly uncertain because the ease of reformulation, the size of consumer response, and the size of the effects of *trans* fat on CHD are uncertain. Also, these changes will occur over time and can be affected by other, unanticipated events. FDA dealt with the uncertainty by estimating a range of possible reductions in CHD associated with the proposed rule. The low and high estimated benefits can be interpreted as a range of potential effects. As the previous section showed, however, the actual realized benefits may exceed the range given by the two methods.

TABLE 4.—METHODS AND SCENARIOS USED TO ESTIMATE BENEFITS

Scenarios		
Scenario 4	Scenario 3	Scenario 2
Margarine reformulation and direct consumer response. All activity begins during the compliance period. Health effects occur 3 years after effective date.	Margarine reformulation, direct consumer response, and some baked goods reformulation. Margarine reformulation and direct consumer response begins during the compliance period. Some baked goods reformulation is completed 5 years after the effective date. Health effects from margarine reformulation, direct consumer response occur 3 years after effective date. Health effects from some baked goods reformulation occur 8 years after effective date.	Margarine reformulation, direct consumer response, and additional baked goods reformulation. Margarine reformulation and direct consumer response begins during the compliance period. Some baked goods reformulation is completed 5 years after the effective date. Additional baked goods reformulation is completed 7 years after the effective date. Health effects from margarine reformulation, direct consumer response occur 3 years after effective date. Health effects from some baked goods reformulation occur 8 years after effective date. Health effects from additional baked goods reformulation occur 10 years after effective date.

Methods	
Low Estimates of Change in CHD Risk	High Estimates of Change in CHD Risk
Assumes that only changes in LDL–C affect risk of CHD.	Assumes that changes in both LDL–C and HDL–C affect risk of CHD.

a. *CHD morbidity and mortality prevented.* FDA calculated the benefits from the proposed rule as the reduction (from the baseline) in CHD multiplied by the value of preventing both fatal and nonfatal cases of CHD. FDA assumed that the cases of CHD prevented by this rule will have the same proportions of fatal and nonfatal cases as currently exists in the population. The American Heart Association estimates that 1.1 million heart attack cases of CHD occur annually, with 33 percent of them fatal. FDA used these estimates as the baseline for the estimated benefits (Ref. 75). The number of cases varies from year to year, so FDA treated the annual number of cases as a distribution with a mean equal to 1.1 million (and a standard deviation of 110,000). FDA applied the estimated decline in the probability of CHD to the baseline to get estimates of the number of cases and fatalities prevented by the proposed rule. FDA estimated the effects using Method 1, which considers changes only in LDL–C, and using Method 2, which considers changes in both LDL–C and HDL–C. With Method 1 FDA estimated that, 3 years, 8 years and 10 years after the effective date, the proposed rule would annually prevent 6,300 cases of CHD and 2,100 deaths, 7,000 cases and 2,300 deaths, and 7,600 cases and 2,500 deaths. With Method 2 FDA estimated that, 3 years, 8 years and 10 years after the effective date, the proposed rule would annually prevent 12,800 cases of CHD and 4,200 deaths, 15,000 cases and 4,900 deaths, and 17,100 cases and 5,600 deaths. Because the association between *trans* fat consumption and CHD via changes in LDL–C is more conclusive, the benefits estimated using Method 1 should be regarded as more certain than the benefits estimated using Method 2.

b. *Value of CHD morbidity and mortality prevented.* The health costs associated with heart attacks were broken down into the costs of fatal and nonfatal events. The cost of a fatal event is the discounted years of life lost multiplied by the dollar value of a quality-adjusted life year. The average years of life lost from fatal CHD are 13, which is about 8.4 years when discounted at 7 percent (Ref. 76). FDA used $100,000 as the value of a life year. That estimate was used by Cutler and Richardson (Ref. 77) and is close to the estimate used by Zarkin et al. (Ref. 68) and the estimate used in the economic analysis of the regulations implementing the 1990

amendments. The average cost per fatal case is, therefore, approximately $840,000 (8.4 x $100,000).

For nonfatal cases, FDA estimated the cost to be the sum of the medical costs, the cost of functional disability, and the cost of pain and suffering. The functional disability, and pain and suffering combine to reduce the quality of life for victims. In a recent study, Cutler and Richardson (Ref. 77) estimated from National Center for Health Statistics data that the quality adjusted life year for a CHD survivor was 0.71, which indicates that the annual loss to the victim is 0.29 quality adjusted years. This loss represents the combined effects of functional disability and pain and suffering. FDA assumed that the loss lasts for 13 years, or 8.4 discounted years. FDA did not estimate the extent to which nonfatal cases reduce life expectancy or increase other health costs. Because nonfatal cases probably do have these effects, FDA may have underestimated the health benefits from preventing nonfatal cases.

The medical costs for nonfatal CHD are also important. The American Heart Association estimates that the cost of a new event is about $22,700 and the total annual costs are $51.1 billion (Ref. 75). If 1.1 million cases lead to $22,700 per case, then all theses cases cost about $25 billion. The remaining 13.9 million cases average about $1,900 per year (($51.1 billion – $25 billion) /13.9 million). FDA, therefore, estimated medical costs per case as $22,700 in the first year and about $1,900 per year thereafter.

The total cost per nonfatal case is the sum of lost quality-adjusted life years multiplied by $100,000 per life year plus the medical costs of $22,700 plus $1,900 per year times the discounted life years. FDA estimated the morbidity cost per case to be about $282,000 ((0.29 x $100,000 x 8.4) + ($1,900 x 8.4) + $22,700).

The annual benefits of the proposed rule equal the number of deaths prevented multiplied by the cost per death, plus the number of nonfatal cases prevented multiplied by the costs per nonfatal case. Because the number of CHD cases and the number of fatalities vary from year to year, FDA estimated the benefits with computer simulations that accounted for the variability.

The estimated benefits reported by the agency are the mean simulated outcomes of Monte Carlo simulations run with 1,000 iterations.

The main uncertainty associated with estimating benefits comes from the lack of knowledge about the correct method linking changes in *trans* fat to changes in CHD. FDA represented model uncertainty by presenting the low results based on the LDL–C alone and the high results based on the combined effects of *trans* fat on LDL–C and HDL–C. Representing uncertainty as a range given by the results for the two methods, however, understates the true uncertainty because it does not account for the possibility of other links between *trans* fat and CHD. If those other links exist, then the benefits of the proposed rule could be much higher than estimated by the agency.

Tables 5 and 6 show the mean of the simulated low and high annual benefits for Scenarios 2 to 4.

TABLE 5.—LOW ESTIMATED BENEFITS OF THE PROPOSED RULE FOR SCENARIOS 2 TO 4 USING METHOD 1 IN MILLIONS OF DOLLARS (BENEFITS DISCOUNTED AT 7 PERCENT IN PARENTHESES)

	Prior to Three Years After Effective Date	Three Years After Effective Date	Four Years After Effective Date	Five Years After Effective Date	Six Years After Effective Date	Seven Years After Effective Date	Eight Years After Effective Date	Nine Years After Effective Date	Ten Years After Effective Date and Later
Scenario 2	$0	$2,919 ($2,383)	$2,919 ($2,227)	$2,919 ($2,081)	$2,919 ($1,945)	$2,919 ($1,818)	$3,226 ($1,877)	$3,226 ($1,809)	$3,409 ($1,733[1])
Scenario 3	$0	$2,919 ($2,383)	$2,919 ($2,227)	$2,919 ($2,081)	$2,919 ($1,945)	$2,919 ($1,818)	$3,226 ($1,877)	$3,226 ($1,809)	$3,226 ($1,691[1])
Scenario 4	$0	$2,919 ($2,383)	$2,919 ($2,227)	$2,919 ($2,081)	$2,919 ($1,945)	$2,919 ($1,818)	$2,919 ($1,699)	$2,919 ($1,588)	$2,919 ($1,484[1])

[1] Discounted values for year ten will continue to decline in later years.

TABLE 6.—HIGH ESTIMATED BENEFITS OF THE PROPOSED RULE FOR SCENARIOS 2 TO 4 USING METHOD 2 IN MILLIONS OF DOLLARS (BENEFITS DISCOUNTED AT 7 PERCENT IN PARENTHESES)

	Prior to Three Years After Effective Date	Three Years After Effective Date	Four Years After Effective Date	Five Years After Effective Date	Six Years After Effective Date	Seven Years After Effective Date	Eight Years After Effective Date	Nine Years After Effective Date	Ten Years After Effective Date and Later
Scenario 2	$0	$5,941 ($4,850)	$5,941 ($4,532)	$5,941 ($4,236)	$5,941 ($3,959)	$5,941 ($3,700)	$6,935 ($4,036)	$6,935 ($3,772)	$7,880 ($4,006[1])
Scenario 3	$0	$5,941 ($4,850)	$5,941 ($4,532)	$5,941 ($4,236)	$5,941 ($3,959)	$5,941 ($3,700)	$6,935 ($4,036)	$6,935 ($3,772)	$6,935 ($3,525[1])
Scenario 4	$0	$5,941 ($4,850)	$5,941 ($4,532)	$5,941 ($4,236)	$5,941 ($3,959)	$5,941 ($3,700)	$5,941 ($3,458)	$5,941 ($3,232)	$5,941 ($3,020[1])

[1] Discounted values for year ten will continue to decline in later years.

Under all scenarios, the benefits are expected to begin 3 years after the effective date. The 3-year lag occurs because CHD is a chronic condition, so a dietary change takes several years to begin to affect the risk of CHD. Under Scenario 3, the benefits increase 8 years after the effective date. The lag for Scenario 3 is the sum of 3-year lag for health effects and the 5 years that FDA expects industry to take to reformulate one-half of the baked goods that can be successfully reformulated. Under Scenario 2, the benefits increase 10 years after the effective date, with 10 years being the sum of the 3-year lag for health effects, the 5 years for industry to reformulate one-half of the baked goods that can be successfully reformulated, and 2 years to reformulate the remaining half of such baked goods. In the next section, on costs, the agency will explain the assumptions behind the lag times used to estimate the reformulation of baked goods.

D. Costs

FDA has identified several different categories of costs that are associated with compliance with this proposed rule. Costs of the regulation include testing costs, decisionmaking costs, relabeling costs, and reformulation costs (including inventory loss). The basic formula is described in Figure 2 of this document. Because FDA has estimated benefits associated with a reduction in *trans* fat consumption due to reformulation, the estimated costs associated with reformulation are included in Figure 2.

FIGURE 2.—BASIC FORMULA FOR COST ESTIMATION

Testing costs per product	X	Number of products tested	=	Total testing costs +
Decisionmaking costs per firm	X	Number of firms needing to test their products	=	Total decisionmaking costs +
Reprinting costs per information panel	X	Number of information panels changed	=	Total information panel reprinting costs +
Relabeling costs per principal display panel	X	Number of principal display panels changed	=	Total relabeling costs for principal display panels +
Reformulation costs (including inventory loss) per product	X	Number of products reformulated	=	Total reformulation costs (including inventory loss) = Total costs

In this analysis, FDA assumed that all product formulations that include partially hydrogenated oil as an ingredient will be tested to determine the quantity of *trans* fat (except for margarine

products, which are all expected to reformulate). The costs are described in section VI.D.2 of this document.

The proposed rule states that, for all products containing 0.5 g or more of *trans* fat per serving, the amount of *trans* fat must be added to the amount of saturated fat in the Nutrition Facts panel and the %DV for saturated fat must be adjusted accordingly. Also, the adjusted amount of saturated fat must be marked with an asterisk, and the amount of *trans* fat must be stated in a footnote to explain the asterisk. To avoid listing *trans* fat in the Nutrition Facts panel, manufacturers may choose to reformulate their products so that they contain less than 0.5 g *trans* fat per serving. FDA has estimated the cost of this decision to relabel or reformulate for each affected firm. These costs are described in section VI.D.3 of this document.

If manufacturers choose to relabel only rather than reformulate, the label for each package size will need to be redesigned and reprinted. These costs are described in section VI.D.4 of this document.

If manufacturers choose to reformulate rather than relabel only, then the new formulation for each product will need to be developed, the production process may need to be altered, new ingredients will need to be purchased, and the new product will need to be consumer tested. These costs are described in sections VI.D.5 and VI.D.6 of this document.

Section VI.C.1.b of this document describes four scenarios for the effects of the rule. Scenario 1: Maximum Response, estimates the benefits of totally eliminating *trans* fats from the diet. The costs corresponding to this scenario have not been estimated because this scenario is not expected to occur as a result of this rule. Scenario 2: Some reformulation and some consumers change their behavior, corresponds to the full long-term costs estimated in this section. Scenario 4: Least reformulation and some consumers change their behavior, corresponds to the near-term costs estimated in this section for testing, decisionmaking costs, relabeling, and margarine product reformulation. Scenario 3 is an intermediate scenario between Scenarios 2 and 4. It would

correspond to the costs for Scenario 4 plus 50 percent of the costs of the baked product reformulation calculated in Scenario 2.

1. Products Affected

The proposed rule covers all food products within the jurisdiction of the FDA. However, not all FDA-regulated products will be affected by the proposed rule: Only products that contain 0.5 g or more of *trans* fat per serving will be required to label the *trans* fat content. Although *trans* fat does occur naturally in some product groups such as dairy foods, it is only likely to be present at levels at or above 0.5 g per serving in products containing partially hydrogenated oils. Therefore, FDA identified the product groups that contain most of the products that use partially hydrogenated oil as an ingredient.

These categories do not cover all products that contain partially hydrogenated oil, but they include the products likely to be affected most by this rule. Focusing the analysis on these product groups allows FDA to use data available on product and label content that are available only by product group. It should be noted, however, that not all of the products in all of these groups contain partially hydrogenated oils.

FDA has used data from its Food Label and Package Survey (FLAPS) data base to estimate the percentage of products in each product group that contain partially hydrogenated oils. Because FDA did not consider the FLAPS data to be sufficiently representative of the Cereal and Refrigerated Spreads product groups for the purpose of this analysis, FDA has used an informal market survey (Ref. 80) to estimate the percentage of these products that contain partially hydrogenated oils. For the Refrigerated Spreads, FDA's informal market survey indicates that 30 percent of the margarine products have already been reformulated to reduce *trans* fat below 0.5 g per serving, some by removing partially hydrogenated oil from the products. Table 7 of this document shows the product groups most affected by this proposal and the percentage and number of products in each group estimated to contain partially hydrogenated oils. Throughout the cost

analysis FDA has used rounded estimates and has rounded the results of calculations. The extent of the rounding is reported in the caption for each table.

TABLE 7.—PRODUCT GROUPS AND NUMBER OF PRODUCTS AFFECTED (NUMBERS ARE ROUNDED TO THE NEAREST TEN, PERCENTAGES ARE ROUNDED TO THE NEAREST 5 PERCENT)

Product Group	Number of Products	Percent of Products Containing Partially Hydrogenated Oil	Number of Products Containing Partially Hydrogenated Oil
Frozen Breakfast Foods (e.g., waffles, pancakes, French toast)	750	80%	600
Cereal (e.g., hot, ready-to-eat and granola types)	1,800	40%	720
Baking Mixes (e.g., mixes for breads, cakes, and cookies)	1,460	75%	1,100
Breading Products (e.g., breading products and croutons)	940	85%	800
Frozen Baked Goods (e.g., pies, bagels, breads, and cookies)	1,510	50%	760
Refrigerated Bread and Pastry Products (e.g., bread dough and sweet roll dough)	1,770	5%	90
Breads (e.g., bread, cakes, doughnuts and sweet rolls)	29,960	50%	14,980
Crackers	1,910	100%	1,910
Cookies	6,940	95%	6,590
Baking Needs (e.g., frostings, chocolate chips, and pie shells)	1,530	65%	1,000
Candy and Gum	14,910	40%	5,960
Shortenings and Oils (e.g., lard, cooking oils, and shortenings)	1,480	15%	220
Refrigerated Spreads (e.g., butter, margarine, and spreads)	1,290	65%	840
Chip Type Snacks (e.g., popcorn, pretzels, potato and corn chips and rice cakes)	10,220	70%	7,150
Total	76,470		42,720

2. Testing Costs

For each of the product groups, FDA used the A. C. Nielsen Database of food products sold in grocery stores with annual sales of $2 million or more to identify the number of product formulations. For the purpose of this analysis, FDA assumed that each of these products would be tested for *trans* fat content. The Refrigerated Spreads group is not included because—as will be explained below—FDA expects all margarine products to be reformulated; there is therefore no reason to test current margarine products. Research Triangle Institute (RTI) collected information on *trans* fat testing costs for FDA. The per product cost of testing for *trans* fat is approximately $200 (Ref. 73). Table 8 shows the number of products in each product group estimated to contain partially hydrogenated oils and the cost of product testing. Total testing costs are estimated to be about $8 million.

TABLE 8.—NUMBER OF PRODUCTS TESTED AND COST OF TESTING BY PRODUCT GROUP (NUMBERS ARE ROUNDED TO THE NEAREST TEN)

Product Group	Number of Products Containing Partially Hydrogenated Oil	Cost of Testing per Product	Cost of Testing per Group
Frozen Breakfast Foods	600	$200	$120,000
Cereal	720	$200	$144,000
Baking Mixes	1,100	$200	$220,000
Breading Products	800	$200	$160,000

TABLE 8.—NUMBER OF PRODUCTS TESTED AND COST OF TESTING BY PRODUCT GROUP (NUMBERS ARE ROUNDED TO THE NEAREST TEN)—Continued

Product Group	Number of Products Containing Partially Hydrogenated Oil	Cost of Testing per Product	Cost of Testing per Group
Frozen Baked Goods	760	$200	$152,000
Refrigerated Bread and Pastry Products	90	$200	$18,000
Breads	14,980	$200	$2,996,000
Crackers	1,910	$200	$382,000
Cookies	6,590	$200	$1,318,000
Baking Needs	1,000	$200	$200,000
Candy, Gum and Cough Drops	5,960	$200	$1,192,000
Shortenings and Oils	220	$200	$44,000
Chip Type Snacks	7,150	$200	$1,430,000
Total	41,880		$8,376,000

FDA used data from the USDA Food Composition Data to estimate the number of products that, when tested, are predicted to be found to contain 0.5 g or more *trans* fat per serving (Ref. 40). The USDA data base contains a list of over 200 food products that were analyzed for *trans* fat content. Where possible, FDA has grouped the foods in the USDA data base into the identified product groups and calculated the percentage of the tested foods in each product group that will be found to contain 0.5 g or more *trans* fat per serving. For some product groups, no foods were found in the USDA data base that contained partially hydrogenated oil. Because these products are similar to products in the Breads product group, FDA used the percentage containing 0.5 g or more *trans* fat from the Breads product group as a proxy. FDA is aware that some margarine products in the Refrigerated Spreads product group have recently been reformulated. Therefore, for this category, FDA used an informal market survey (Ref. 80) to estimate the number of margarine products containing 0.5 g or more *trans* fat. Table 9 of this document shows the percentage of foods in each product group that are estimated to contain 0.5 g or more of *trans* fat.

TABLE 9.—PERCENTAGE AND NUMBER OF PRODUCTS CONTAINING 0.5 GRAM (g) OR MORE *trans* FAT PER SERVING (NUMBERS ARE ROUNDED TO THE NEAREST TEN)

Product Group	Number of Products Containing Partially Hydrogenated Oil	Percentage of Products Containing Partially Hydrogenated Oil Also Containing 0.5 g or More *Trans* Fat per Serving	Number of Products Containing 0.5 g or More *Trans* Fat per Serving
Frozen Breakfast Foods	600	70%[1]	420
Cereal	720	40%	290
Baking Mixes	1,100	70%[1]	770
Breading Products	800	70%[1]	560
Frozen Baked Goods	760	70%[1]	530
Refrigerated Bread and Pastry Products	90	70%[1]	60

TABLE 9.—PERCENTAGE AND NUMBER OF PRODUCTS CONTAINING 0.5 GRAM (g) OR MORE *trans* FAT PER SERVING (NUMBERS ARE ROUNDED TO THE NEAREST TEN)—Continued

Product Group	Number of Products Containing Partially Hydrogenated Oil	Percentage of Products Containing Partially Hydrogenated Oil Also Containing 0.5 g or More *Trans* Fat per Serving	Number of Products Containing 0.5 g or More *Trans* Fat per Serving
Breads	14,980	70%	10,490
Crackers	1,910	100%	1,910
Cookies	6,590	100%	6,590
Baking Needs	1,000	100%	1,000
Candy, Gum and Cough Drops	5,960	70%	4,170
Shortenings and Oils	220	80%	180
Refrigerated Spreads	840	80%	670
Chip Type Snacks	7,150	60%	4,290
Total	42,720		31,930

[1] Estimate from the breads product group used as a proxy.

3. Decisionmaking Costs

To comply with this rule, firms will need to gain an understanding of the policy of the regulation, interpret that policy for their products, and determine the scope and coverage through analytical testing. Those firms that determine through testing that they are making products that contain 0.5 g or more of *trans* fat per serving will need to determine the options they have for compliance, gather information on the implications of each option, and decide whether to only relabel or to reformulate these products. The costs of all these decisionmaking activities are the decisionmaking costs of the rule.

Several factors affect the size of decisionmaking costs, including the complexity of the regulation, the number of distinct products affected, the size of the firm, and the length of the compliance period. This proposal involves analytical testing and product reformulation, and, therefore, compliance with it demands significant decisionmaking effort. The more products that a firm makes that are affected by a regulation, the greater the decisionmaking effort needed to determine the compliance strategy of the firm. These factors largely explain why large firms typically have higher decisionmaking costs than do small firms. An additional factor relating to firm size is that large firms typically have more complex (and costly) decisionmaking processes than do small firms. Finally, longer compliance periods (the length of time between the publication of the final rule and the effective date of the regulation) reduce decisionmaking costs, because

there is less need for overtime and for the rescheduling of planned activities. Within the compliance periods considered, a doubling of the compliance period cuts decisionmaking costs in half. The estimate of decisionmaking costs presented here is based on a 2-year compliance period.

For the purpose of this analysis, FDA assumes that each of the firms that make products containing 0.5 g or more *trans* fat per serving will bear decisionmaking costs for a complex regulation.

To estimate the number of these firms, FDA estimated the total number of firms that make foods in each product group. Next, FDA estimated the percentage of these firms (by group product) that make foods containing 0.5 g or more *trans* fat per serving. FDA expects these firms to bear decisionmaking costs for compliance with this rule.

Precise data are not available on the number of firms that make foods for each product group. Instead, FDA has used data from Dun and Bradstreet Market Identifiers to estimate the number of firms making food in each Standard Industry Classification (SIC) most closely related to each product group. Table 10 shows each product group along with the SIC code that most closely corresponds to each product group. It also shows the number of small and large firms producing food in each category. FDA has used the Small Business Administration (SBA) guidelines to define small businesses in each SIC. Unless otherwise noted, a small business is defined as one having 500 or fewer employees.

TABLE 10.—NUMBER OF FIRMS MAKING PRODUCTS IN EACH PRODUCT GROUP (NUMBERS ARE ROUNDED TO THE NEAREST TEN)

Product Group	Dun & Bradstreet Market Identifier SIC	Number of Small Firms	Number of Large Firms	Total Number of Firms
Frozen Breakfast Foods	20389901, 20389904, 20389910	10	10	20
Cereal	2043	60[1]	10	70
Baking Mixes	204103	40	20	60
Breading Products, Frozen Baked Goods, Refrigerated Bread and Pastry Products, Breads	2051	3,000	1,340	4,340
Crackers Cookies	2052	660[2]	280	940
Baking Needs, Candy, Gum, and Cough Drops	206499	430	20	450
Shortenings and Oils, Refrigerated Spreads	207901, 207902, 207999	80[2]	20	100
Chip Type Snacks	2096	320	90	410
Total		4,600	1,790	6,390

[1] Small business is defined as 1,000 employees or fewer.
[2] Small business is defined as 750 employees or fewer.

FDA has information on the percentage of products in each product group that contain 0.5 g or more of *trans* fat, but it does not have information on the percentage of firms in each category that make such products. To estimate the number of firms affected by the rule, FDA assumed that when a small percentage of products contain 0.5 g or more *trans* fat per serving, then a proportionally smaller percentage of firms are making such products. Conversely, when a large percentage of products in a product group contain 0.5 g or more *trans* fat per serving, then a proportionally larger percentage of firms are making such products. In other words, FDA assumed that individual firms are more likely to make products that are similar in composition to the preponderance of products on the market and less likely to make products that are different in composition.

To translate the estimate of the percentage of products that contain 0.5 g or more of *trans* fat into an estimate of the percentage of firms making such products, FDA has used the cumulative normal distribution with a mean of 0.5 and a standard deviation of 0.2. Graphically, this relationship is slightly S-shaped (a standard deviation larger than 0.2 would yield a more pronounced S-shape). Using a mean of 0.5 yields the result that when 50 percent of the products contain 0.5 g or more *trans* fat per serving, then 50 percent of the firms are estimated to be making such products.

Where FDA combined different product groups to fit within a single SIC, it averaged the percentages of products with 0.5 g or more *trans* fat per serving in the product group. Table 11 of this document shows the percentage and number of firms by size in each SIC estimated to make products containing 0.5 g or more *trans* fat per serving. FDA assumed that small firms are just as likely to make products containing 0.5 g or more *trans* fat per serving as large firms are.

TABLE 11.—PERCENTAGE AND NUMBER OF FIRMS BY SIZE MAKING PRODUCTS CONTAINING 0.5 GRAM (g) OR MORE *trans* Fat per Serving (numbers are rounded to the nearest ten, percentages are rounded to the nearest 5 percent)

Dun & Bradstreet Market Identifier SIC	Percentage of Products Containing 0.5 g or More *trans* Fat per Serving	Percentage of Firms Making Products Containing 0.5 g or More *trans* Fat per Serving	Number of Small Firms Making Products Containing 0.5 g or More *Trans* Fat per Serving	Number of Large Firms Making Products Containing 0.5 g or More *Trans* Fat per Serving
20389901,04,10	55%	60%	10	10
2043	15%	5%	0	0
204103	55%	60%	20	10
2051	30%	15%	450	200

TABLE 11.—PERCENTAGE AND NUMBER OF FIRMS BY SIZE MAKING PRODUCTS CONTAINING 0.5 GRAM (g) OR MORE *trans* Fat per Serving (numbers are rounded to the nearest ten, percentages are rounded to the nearest 5 percent)—Continued

Dun & Bradstreet Market Identifier SIC	Percentage of Products Containing 0.5 g or More *trans* Fat per Serving	Percentage of Firms Making Products Containing 0.5 g or More *trans* Fat per Serving	Number of Small Firms Making Products Containing 0.5 g or More *Trans* Fat per Serving	Number of Large Firms Making Products Containing 0.5 g or More *Trans* Fat per Serving
2052	95%	100%	660	280
206499	30%	15%	60	0
207901,02,99	50%	50%	40	10
2096	40%	30%	100	30
Total			1,340	540

FDA used the Food Labeling Cost Model developed by RTI for the NLEA rules to estimate the per firm decisionmaking costs borne by firms for this rule (Ref. 74). FDA did not directly apply the RTI model of costs. Instead, the agency assumed that the decisionmaking costs per firm for the proposed rule would be similar in magnitude—although not identical in detail—to the administrative costs per firm in the RTI model. In other words, the agency assumed that the level of effort but not the decisions involved were the same for the firms affected by the proposed rule and the firms in the RTI model. FDA estimates the decisionmaking costs to be $3,500 for a small firm and $25,000 for a large firm. Table 12 of this document shows the estimated decisionmaking costs for the rule.

TABLE 12.—PERCENTAGE AND NUMBER OF FIRMS BY SIZE MAKING PRODUCTS CONTAINING 0.5 GRAM (g) OR MORE *trans* FAT PER SERVING (NUMBERS ARE ROUNDED TO THE NEAREST TEN)

Dun & Bradstreet Market Identifier SIC	Number of Small Firms Making Products Containing 0.5 g or More *trans* Fat per Serving	Number of Large Firms Making Products Containing 0.5 g or More *trans* Fat per Serving	Decisionmaking Cost for Small Firms per SIC	Decisionmaking Cost for Large Firms per SIC
20389901,04,10	10	10	$35,000	$250,000
2043	0	0	$0	$0
204103	20	10	$70,000	$250,000
2051	450	200	$1,575,000	$5,000,000
2052	660	280	$2,310,000	$7,000,000
206499	60	0	$210,000	$0
207901,02,99	40	10	$140,000	$250,000
2096	100	30	$350,000	$750,000
Total	1,340	540	$4,690,000	$13,500,000

Total decisionmaking costs of the rule are estimated to be about $18 million.

4. Relabeling Costs

The two areas of a product's label that may be changed are: (1) The information panel (to alter the saturated fat line and add the footnote to the nutrition label or to change the list of

ingredients), and (2) the principal display panel (to remove claims). Each firm must choose whether to change only the labels of existing products to reflect the proposed changes or to reformulate products to reduce or eliminate *trans* fat and relabel the reformulated products appropriately. If a firm chooses to reformulate a product, it will have to change the product's ingredient list. Therefore, regardless of how a firm chooses to comply with this rule, all labels of all products currently containing 0.5 g or more of *trans* fat will have to be changed to reflect changes in either the Nutrition Facts panel or the ingredient list or both. The cost to change the Nutrition Facts panel is equivalent to the cost to change the ingredient list.

a. *Changes to the information panel.* The number of labels that will be changed is greater than the number of products that contain 0.5 g or more *trans* fat because product formulations come in various-sized packages. For example, for a cracker product that contains 0.5 g or more *trans* fat per serving and that is sold in 3 different-sized packages, the labels of each of the 3 packages must be changed.

For each of the product groups, FDA used the A. C. Nielsen Database of food products sold in grocery stores with annual sales of $2 million or more to identify the number of food labels. Using this data base for each product group, FDA has calculated the ratio of the number of labels stockkeeping units (SKU's) to the number of products. FDA then multiplied the number of products estimated to contain 0.5 g or more *trans* fat per serving with this SKU/product ratio to estimate the number of labels that will be changed.

FDA has based its estimate of the cost of changing each information panel on the expectation of a three-color change and a 2-year compliance period. The cost of changing labels varies across product groups because the type of package and label varies. For example, if the label is attached to the package, the cost of the label change is less than if the label is an integrated part of the package. With a 2-year compliance period, there should be no label inventory loss.

Table 13 of this document shows the estimated number of labels to be changed in each product group and the cost of the label change. Total information panel relabeling costs are estimated to be about $30 million.

TABLE 13.—NUMBER OF INFORMATION PANELS CHANGED AND COST OF REPRINTING (NUMBERS ARE ROUNDED TO THE NEAREST TEN, DOLLARS ARE ROUNDED TO THE NEAREST HUNDRED)

Product Group	Number of SKU's[1] for Products Containing 0.5 gram or More *Trans* Fat per Serving	Reprinting Cost per SKU	Reprinting Cost per Product Group
Frozen Breakfast Foods	460	$1,000	$460,000
Cereal	370	$0[2]	$0
Baking Mixes	880	$300	$264,000
Breading Products	0	$1,300	$0
Frozen Baked Goods	620	$1,300	$806,000
Refrigerated Bread and Pastry Products	70	$1,300	$91,000
Breads	12,800	$1,300	$16,640,000
Crackers	2,270	$500	$1,135,000
Cookies	8,170	$500	$4,085,000
Baking Needs	1,150	$800	$920,000
Candy, Gum, and Cough Drops	5,340	$800	$4,272,000
Shortenings and Oils	280	$100	$28,000
Refrigerated Spreads	730	$100	$73,000
Chip Type Snacks	5,530	$200	$1,106,000
Total	38,670		$29,880,000

[1] Stockkeeping units.
[2] Cereal product labels are changed so frequently that the reprinting cost of changing an information panel with a three-color change and a 2-year compliance period amounts to a cost of less than $50 per SKU.

b. *Changes to principal display panel.* In addition to changes that will be required to change the Nutrition Facts panel or to change the ingredient statement, there will be label changes required for a smaller number of products because of the loss of nutrient content claims about saturated fat or cholesterol. These changes are likely to involve changes to the principal display panel and other marketing-related labeling. FDA assumed that claims in the Refrigerated Spread product group are on margarine products that will be reformulated. Therefore, claims on these products will not be affected. Costs to make these changes are related to both costs per SKU (Table 14 of this document) and costs per firm (Table 15 of this document).

The types of claims affected by this proposal are low and reduced saturated fat claims; cholesterol free, low cholesterol, and reduced cholesterol claims; lean and extra lean claims; healthy claims; and four health claims with established qualifying levels of saturated fat as follows: (1) Fat and the risk of cancer (through the saturated fat criterion for extra lean, § 101.73); (2) dietary saturated fat and cholesterol and the risk of coronary heart disease (§ 101.75); (3) fruits, vegetables,

and grain products that contain fiber and the risk of coronary heart disease (§ 101.77); and (4) soluble fiber from certain grains and the risk of coronary heart disease (§ 101.81). The cost estimate in this section only refers to the effects of this proposal on the relevant saturated fat and cholesterol claims. FDA does not have sufficient information on the number of SKU's with the lean, extra lean, or healthy claims or the four health claims to include them in this analysis. FDA believes that not including these costs does not result in a serious underestimation of the costs of this proposal and requests comments on this issue.

To determine the number of SKU's with affected claims, FDA multiplied the number of products in each product group with such saturated fat or cholesterol claims by the percentage of products in the product group estimated to have 0.5 g or more *trans* fat per serving. FDA then multiplied the result by the SKU/product ratio for the product group.

FDA does not have information to estimate the percentage of existing saturated fat and cholesterol claims that could not continue to be made under this proposal. For the purpose of this analysis, FDA assumed that 50 percent of these claims would be lost. That a significant portion of claims would be lost is reasonable, because producers are likely to be making claims on many products that are nutritionally very near the qualifying limit for the claim. More stringent qualifying levels for the claims are likely to affect the presumably large percentage of products that are clustered close to the existing qualifying levels. FDA's assumptions yield an estimate that less than eight percent ((2,990 ÷ 38,670) x 100) of the number of SKU's for products containing 0.5 g or more *trans* fat per serving will have changes to the principal display panel.

Several factors determine the cost of relabeling for claim changes. There are costs for market testing of a new design for the principal display panel to replace the design of the panel that had been previously accepted in the market when the product was able to bear the claim. There are costs for redesign and reprinting of the principal display panel. There are also costs for administrative activities associated with removing the claim from all marketing and labeling.

FDA has used the RTI Labeling Model to estimate the per SKU redesign and printing costs associated with the change in the principal display panel. Table 14 of this document shows the number of SKU's estimated to need changes in the principal display panel and the redesign and printing costs of such changes.

TABLE 14.—NUMBER OF PRINCIPAL DISPLAY PANELS CHANGED AND COST OF REDESIGN AND REPRINTING (NUMBERS ARE ROUNDED TO THE NEAREST TEN)

Product Group	Number of SKU's[1] *Changed for Claims*	Cost per SKU	Cost per Product Group
Frozen Breakfast Foods	40	$1,900	$76,000
Cereal	40	$0	$0
Baking Mixes	30	$600	$18,000
Breading Products	0	$2,500	$0
Frozen Baked Goods	40	$2,500	$100,000
Refrigerated Bread and Pastry Products	0	$2,500	$0
Breads	640	$2,500	$1,600,000
Crackers	590	$800	$472,000
Cookies	1,350	$800	$1,080,000
Baking Needs	20	$1,500	$30,000
Candy, Gum, and Cough Drops	0	$1,500	$0
Shortenings and Oils	20	$100	$2,000
Chip Type Snacks	220	$300	$66,000
Total	2,990		$3,444,000

[1] Stockkeeping units.

FDA adapted information from the RTI labeling model to estimate the additional costs associated with changing principal display panels. These additional costs consist of market testing costs and marketing administrative costs. FDA estimates market testing costs—the costs of employee taste panels, consumer focus groups, and other marketing tests—to be $2,000 per product for small firms and $23,500 per product for large firms. Marketing administrative costs include planning the change to a new label, making decisions about the appearance of the new principal display panel, and monitoring the marketing tests. The agency did not have direct estimates of these administrative marketing costs per product, but industry sources have asserted that these costs are at least as large as the market testing costs. The agency assumed that marketing administrative costs per product would be about the same as the administrative costs per firm associated with a complex labeling rule in the RTI labeling model because the amounts of effort were similar. The estimates of marketing administrative costs are $3,500 per product for small firms and $25,000 per product for large firms. FDA, therefore estimates the total cost per product of changing a principal display panel to be $5,500 for small firms and $48,500 for large firms. The estimates

for these costs are applied per product as a weighted average based on the percentage of products made by small and large firms taken from the Enhanced Establishment Database of FDA-inspected firms developed by RTI (Ref. 73).

Table 15 of this document shows the number of products estimated to need changes in the principal display panel and the cost of market testing and administrative activity. Total principal display panel relabeling costs are estimated to be about $43 million ($3 million for redesign and printing plus $40 million for market testing and administrative activity). These costs do not include the cost to producers of the lost value of the firm-specific capital developed by marketing under existing claims or the cost to consumers of searching for and switching to new products.

TABLE 15.—NUMBER OF PRINCIPAL DISPLAY PANELS CHANGED AND COST OF MARKETING CHANGES AND ADMINISTRATIVE ACTIVITIES (NUMBER OF PRODUCTS ARE ROUNDED TO THE NEAREST TEN, DOLLARS ROUNDED TO THE NEAREST THOUSAND)

Product Group	Number of Products Changed for Claims	Average Cost per Product	Cost per Product Group
Frozen Breakfast Foods	40	$20,000	$800,000
Cereal	30	$19,000	$570,000
Baking Mixes	30	$16,000	$480,000
Breading Products	0	$14,000	$0
Frozen Baked Goods	30	$14,000	$420,000
Refrigerated Bread and Pastry Products	0	$14,000	$0
Breads	520	$14,000	$7,280,000
Crackers	500	$17,000	$8,500,000
Cookies	1,090	$17,000	$18,530,000
Baking Needs	20	$14,000	$280,000
Candy, Gum, and Cough Drops	0	$14,000	$0
Shortenings and Oils	10	$17,000	$170,000
Chip Type Snacks	170	$15,000	$2,550,000
Total	2,440		$39,580,000

5. Margarine Reformulation Costs

The proposal states that if a product contains 0.5 g or more *trans* fat, then its label must meet certain requirements. Manufacturers may comply with this rule in either of two ways: (1) Relabel the product so that it complies with the rule, or (2) reformulate the product so that it contains less than 0.5 g of *trans* fat and will not be affected by the rule. When manufacturers are faced with reporting more saturated fat than previously reported, as well as revealing the presence of *trans* fat that consumers had not previously realized was present, reformulation is a likely response to avoid the reduced demand for products with labeled *trans* fat. Therefore, FDA has estimated the costs of both of these compliance choices.

FDA assumes that producers will decide whether or not to reformulate on a product-by-product basis. They will choose to reformulate when the expected private benefits minus the expected private costs of reformulating the product exceed the expected private benefits minus expected private costs of just relabeling the product. In other words, if a product is expected to lose market share because of the new disclosure, then manufacturers must compare lost sales to the cost of reformulation.

FDA expects that, in the near term, manufacturers will reformulate all margarine products containing 0.5 g or more of *trans* fat per serving in response to this rule. The following five pieces of information support this expectation. First, in Germany and some other European countries, the actual, demonstrated market response to consumer concern about *trans* fat is that all margarine products have been reformulated to eliminate *trans* fat. Second, many people who currently consume margarine products are likely to do so to consume less saturated fat than is in butter. Because the rule would raise the reported amount of saturated fat on any unreformulated margarine products, these margarine consumers are likely to search for margarine products with lower levels of reported saturated fat. Third, publicity of the issue by consumer groups has highlighted margarine as a source of *trans* fat and has given prominent attention to reformulated margarine products. As more margarine products are reformulated, the emphasis of publicity by consumer groups will probably shift to calling attention to any remaining margarine products that do not reformulate. Fourth, information from RTI indicates that producers of margarine know more about the reformulation of margarine products than producers of other products know about the reformulation of those products and that, on the whole, U.S. margarine producers plan to reformulate to eliminate *trans* fat (Ref. 73). Fifth, by an informal market survey (Ref. 80), FDA estimates that 30 percent of margarine products in the United States have already, before publication of this proposal, been reformulated to eliminate *trans* fat.

For this analysis, FDA estimates that this rule will result in the reformulation of all 670 remaining margarine products that contain *trans* fat to reduce *trans* fat below 0.5 g per serving within a 2-year compliance period.

The reformulation of food products is a very costly process. Although the process is likely to vary from company to company, the following provides a description of a typical process. FDA requests information on processes different from that described here. First, management, in conjunction with research and development, must determine which products are the best candidates to be reformulated. Next, laboratories (either in-house or out-source) are used to develop a new formula with acceptable characteristics for consumers. Then, an investigation must be made to determine that the new ingredients are available in sufficient quantity and at an acceptable price. Also, in the case of food additives, it may be necessary to determine that the new ingredients are approved for use in the food being reformulated. It may also be necessary to find a source for new equipment. If all of these activities do not rule out a new formulation, then a test kitchen is used to make the product in small batches. In the test kitchen, some new formulations will be rejected and others will be improved.

Those new formulations that are found acceptable in the test kitchen are then tested in a pilot plant. The difference between the test kitchen and the pilot plant can be dramatic. Formulations that work well in small batches may be totally unacceptable when produced on a large scale. If tests at the pilot plant go well, then trials of the new formulation begin at actual, full-scale processing plants. A crucial issue for large-scale, commercial production is whether existing equipment is adaptable to the new product formulation. After all of these stages, if a new formulation is acceptable for large-scale, commercial production, then there are costs of label redesign, marketing, management and employee training, the purchase of new ingredients, and some inventory loss of either old labels or old ingredients (because the labels must match the ingredients). This entire process is time-intensive, taking about 1 year, on average. In general, large firms will have the capacity to perform all of these steps in-house, whereas small firms will contract out

most of them. Nevertheless, on a per product basis, the process is the same for large and small firms.

FDA has made an estimate of the cost of reformulation based on information on the cost of reformulating tortilla chips supplied by industry (Ref. 78). The costs of reformulation are divided into three categories: (a) Formulation development and testing costs, (b) inventory loss, and (c) ingredient costs. As described in the following sections, the total cost of margarine reformulation because of this rule is estimated to be $302 million.

a. *Formulation development and testing costs.* The formulation development process is estimated to require approximately 5,000 hours of professional time (product scientists, sensory scientists, analytical chemists, manufacturing engineers, and quality control scientists) at $30 per hour per product. This estimate of labor time may be low. It assumes that the first attempt at reformulation is fully successful. Additionally, there are operating expenses for the laboratories, the pilot plants, and the switchover and retooling of manufacturing plants. Finally, there are costs for market testing to determine that the new formulation is acceptable to consumers for the entire shelf life of the product. The shelf-life issue has a significant impact on the amount of time required to market a new formulation. For example, if a product has a shelf life of 2 years, then a new formulation for the product cannot be approved for production until the new formulation has been shelved for 2 years. Table 16 of this document shows the estimated per product formulation development and testing costs. FDA considers these estimates to be uncertain because of the limited amount of information available at this time and requests comment on the cost of reformulation on a product specific basis.

TABLE 16.—FORMULATION DEVELOPMENT AND TESTING COSTS PER PRODUCT

Category	Cost
Professional Labor (5,000 hours at $30 per hour)	$150,000
Development Facility Operation	$190,000
Market Testing	$100,000
Total	$440,000

The total cost of formulation development and testing for the 670 margarine products that would be reformulated near-term because of this rule is $295 million.

b. *Inventory loss.* A loss of inventory of either labels for the old formulation or ingredients that are not included in the new formulation is expected. The loss of label inventory can be reduced to zero with a long enough compliance period. However, the reformulation of a product requires a simultaneous change of ingredients and labels. Because both ingredients and labels must be ordered months in advance, it is difficult to order the amount of ingredients and labels such that both are used up completely in the same package.

The actual cost of inventory loss depends on how closely producers are able to coordinate the use of ingredients and labels and on the cost of disposing of the surplus ingredients or labels. FDA assumed a fixed amount of $10,000 per SKU for this cost. The total cost of inventory loss for the 730 margarine SKU's that will be reformulated because of this rule is $7 million.

c. *Ingredient costs.* For margarine reformulation, FDA has estimated no increase in ingredient costs, because the price of reformulated margarine products that are already on the market is no higher than the price of margarine products containing 0.5 g or more per serving of *trans* fat. The different ingredients used in the products appear to have had no impact on the cost of production. However, as greater numbers of products are reformulated, the increased demand for the substitute ingredients may increase costs. FDA requests comments on this aspect of costs.

6. Baked Products Reformulation

In addition to the near term reformulation of margarine products expected within the compliance period of the rule, FDA expects that in the long term some baked products (product groups Breads (including cakes), Crackers, and Cookies) will be reformulated. On average, these products contain large amounts of *trans* fat relative to the amounts of saturated fat that they contain. FDA's estimate of the amount of reformulation in these product groups is based on two factors: (1) The number of claims potentially lost because of the rule, and (2) the size of the producing firm.

As described in section VI.D.4.b of this document, only 50 percent of the SKU's with claims are assumed to lose those claims. Therefore, only 50 percent of the SKU's with claims are likely to be candidates for reformulation.

Because reformulation is so expensive on a per product basis, FDA assumed that only large firms making these products will reformulate. Also, in the absence of information, FDA assumed that each large firm is just as likely as each small firm is to make a product with a claim. Therefore, the percentage of products losing claims that will be reformulated is equivalent to the percentage of large firms making products containing 0.5 g or more *trans* fat. Table 17 of this document shows the estimate of the number of products that will be reformulated.

FDA is assuming that only a very small percentage of the products in these categories will be reformulated because of the cost of reformulation and the limited consumer appeal (in terms of market share) that foods with health claims in these categories have had thus far. If producers perceive that consumers will respond more negatively to the information on *trans* fat than they have responded thus far to the information on saturated fat, then the actual number of products reformulated may be greater. If that happens, the actual costs of the rule will be greater than those estimated here. However, the benefits will increase to an even greater degree, so that the net benefits of the rule will be even greater than estimated in this analysis.

TABLE 17.—NUMBER OF SKU'S[1] AND PRODUCTS LOSING CLAIMS DUE TO CHANGES IN QUALIFICATIONS FOR CLAIMS AND NUMBER OF PRODUCTS REFORMULATED BY LARGE FIRMS (NUMBERS ARE ROUNDED TO THE NEAREST TEN)

Product Group	Number of SKU's Losing Claims	Number of Products Losing Claims	Number of Products Reformulated Long Term (made by large firms)	Products Reformulated as a Percentage of Total Products Containing 0.5 gram or more *trans* Fat per Serving
Breads	640	530	160	1.5%
Crackers	590	500	150	8%
Cookies	1,350	1,090	330	5%
Total			640	3%

[1] Stockkeeping units.

Because FDA has no specific information on the timing of reformulation, FDA assumed that the reformulation for these baked products would be divided evenly into two stages. In stage 1, producers will attempt to reformulate products with the best potential for reformulation. In stage

2, producers will make use of the products, knowledge and technologies developed in stage 1 of reformulation to reformulate a second set of products.

Stage 1 of products is assumed to take 5 years of ongoing labor effort in the product development facilities to develop a satisfactory reformulation for these products. The effort is expected to be fully successful only in the fifth year. The product development teams involved in the stage 1 reformulation effort should learn a great deal about the reformulation of baked products in the process. Therefore, FDA assumes that reformulation of the stage 2 of products will take 2 years of ongoing labor effort in the product development facilities.

Tables 18 and 19 of this document show the expected annual cost per product of the reformulation development process in both stages of reformulation along with the present value of the costs for each year. The total discounted present value of the cost of stage 1 reformulation activity is about $1 million per product and about $400,000 for stage 2 reformulation activity.

FDA has not attempted to estimate the ongoing increased cost of substitutes for partially hydrogenated oil. Competition provides producers with incentives to use the least expensive ingredients that are acceptable for the quality of product they are making. Therefore, in general, any change in existing formulations (such as is expected to occur as a result of this rule) will increase the cost of ingredients. Even a very small increase in the price of a minor ingredient can amount to an increase in production costs of millions of dollars when multiplied by millions of units. However, FDA does not have sufficient information on the types of substitutes that will be used, on the volume of substitutes that will be needed, on the future price of the substitutes at the time that reformulation is completed, or on the increase in price that could be expected as a result of reformulation of a sizable part of the food industry. For this reason the estimated cost of reformulation presented here is likely to be an underestimate of the true cost. Also, FDA has not included the cost of relabeling the reformulated baked good products. This cost would be so small in comparison to the costs of reformulation that it would not change the discounted estimate at the level of precision used here.

TABLE 18.—EXPECTED ANNUAL AND DISCOUNTED COST OF LONG-TERM REFORMULATION DEVELOPMENT PROCESS FOR A SINGLE BAKED PRODUCT IN STAGE 1 (DOLLARS ARE ROUNDED TO THE NEAREST THOUSAND)

Year	Category	Annual Expenditure	Present Value (discounted at 7%)
1	Labor ($150,000) and facilities ($50,000)	$200,000	$187,000
2	Labor ($150,000) and facilities ($50,000)	$200,000	$175,000
3	Labor ($150,000) and facilities ($50,000)	$200,000	$163,000
4	Labor ($150,000) and facilities ($50,000)	$200,000	$153,000
5	Fully successful reformulation ($450,000)	$450,000	$321,000
Total			$999,000

TABLE 19.—EXPECTED ANNUAL AND DISCOUNTED COST OF LONG-TERM REFORMULATION DEVELOPMENT PROCESS FOR A SINGLE BAKED PRODUCT IN STAGE 2 (DOLLARS ARE ROUNDED TO THE NEAREST THOUSAND)

Year	Category	Annual Expenditure	Present Value (discounted at 7%)
6	Labor ($150,000) and facilities ($50,000)	$200,000	$133,000
7	Fully successful reformulation ($450,000)	$450,000	$280,000
Total			$413,000

Table 20 of this document shows the total discounted cost of both stages of long term reformulation for these baked product categories.

TABLE 20.—DISCOUNTED COST OF LONG-TERM BAKED GOOD REFORMULATION (NUMBERS OF PRODUCTS ARE ROUNDED TO THE NEAREST FIVE, DOLLARS ARE ROUNDED TO THE NEAREST THOUSAND)

Product Group	Number of Baked Products Reformulated in Stage 1 (made by large firms)	Discounted Cost of Reformulation in Stage 1	Number of Baked Products Reformulated in Stage 2 (made by large firms)	Discounted Cost of Reformulation in Stage 2
Breads	80	$80,000,000	80	$33,000,000
Crackers	75	$75,000,000	75	$31,000,000
Cookies	165	$165,000,000	165	$68,000,000
Total	320	$320,000,000	320	$132,000,000

7. Cost Summary

In summary, Table 21 of this document provides an overview of the extent of the effect of the rule on products and firms in each product group significantly affected.

TABLE 21.—SUMMARY OF NUMBER OF PRODUCTS, FIRMS, AND LABELS AFFECTED

Product Group	Number of Products Tested	Number of Products With 0.5 gram or More *trans* Fat per Serving	Number of Firms with Decisionmaking Costs	Number of Information Panels Changed	Number of Principal Display Panels Changed	Number of Products Reformulated
Frozen Breakfast Foods	600	420	20	460	40	0
Cereal	720	290	0	370	40	0
Baking Mixes	1,100	770	30	880	30	0
Breading Products	800	560	650	0	0	0
Frozen Baked Goods	760	530		620	40	0
Refrigerated Bread and Pastry Products	90	60		70	0	0
Breads	14,980	10,490		12,800	640	160
Crackers	1,910	1,910	940	2,270	590	150
Cookies	6,590	6,590		8,170	1,350	330
Baking Needs	1,000	1,000	60	1,150	20	0
Candy, Gum, and Cough Drops	5,960	4,170		5,340	0	0

TABLE 21.—SUMMARY OF NUMBER OF PRODUCTS, FIRMS, AND LABELS AFFECTED—Continued

Product Group	Number of Products Tested	Number of Products With 0.5 gram or More *trans* Fat per Serving	Number of Firms with Decisionmaking Costs	Number of Information Panels Changed	Number of Principal Display Panels Changed	Number of Products Reformulated
Shortenings and Oils	220	180	50	280	20	0
Refrigerated Spreads	0	670		730	0	670
Chip Type Snacks	7,150	4,290	130	5,530	220	0
Total	41,880	31,930	1,880	38,670	2,990	1,310

To provide cost estimates on the same basis as the benefits estimates, total costs of the rule are estimated in terms of the three scenarios that are likely from section VI.C.1.b of this document. Tables 22, 23, and 24 of this document show the total estimated cost of the scenarios. FDA has not estimated the distribution of the burden of costs between producers and consumers. The agency expects that some fraction of the costs—as measured at the producer's stage—will be passed on to consumers in the form of increases in the prices of the foods covered by the proposed rule.

TABLE 22.—COSTS FOR SCENARIO 2: FULL LONG-TERM YEARLY TOTAL COSTS IN MILLIONS (DISCOUNTED COSTS IN PARENTHESES)[1]

Cost Category	During Compliance Period	One Year After Effective Date	Two Years After Effective Date	Three Years After Effective Date	Four Years After Effective Date	Five Years After Effective Date	Six Years After Effective Date	Seven Years After Effective Date	Eight Years After Effective Date and Later
Testing costs	$8								
Decisionmaking costs	$18								
Relabeling costs	$73								
Margarine reformulation costs	$302								
Baked products reformulation costs		$64 ($60)	$64 ($56)	$64 ($52)	$64 ($49)	$144 ($103)	$64 ($43)	$144 ($90)	$0
Total costs	$401	$64 ($60)	$64 ($56)	$64 ($52)	$64 ($49)	$144 ($103)	$64 ($43)	$144 ($90)	$0

[1] Reformulation of all margarine products and some baked products plus some consumer response to the labeling.

TABLE 23.—COSTS FOR SCENARIO 4: NEAR-TERM YEARLY TOTAL COSTS IN MILLIONS (DISCOUNTED COSTS IN PARENTHESES)[1]

Cost Category	During Compliance Period	One Year After Effective Date	Two Years After Effective Date	Three Years After Effective Date	Four Years After Effective Date	Five Years After Effective Date	Six Years After Effective Date	Seven Years After Effective Date	Eight Years After Effective Date and Later
Testing costs	$8								
Decisionmaking costs	$18								
Relabeling costs	$73								
Margarine reformulation costs	$302								
Total costs	$401	$0	$0	$0	$0	$0	$0	$0	$0

[1] Reformulation of all margarine products plus some consumer response to the labeling.

TABLE 24.—COSTS FOR SCENARIO 3: NEAR-TERM COSTS PLUS 50 PERCENT OF FULL LONG-TERM YEARLY TOTAL COSTS IN MILLIONS (DISCOUNTED COSTS IN PARENTHESES)[1]

Cost Category	During Compliance Period	One Year After Effective Date	Two Years After Effective Date	Three Years After Effective Date	Four Years After Effective Date	Five Years After Effective Date	Six Years After Effective Date	Seven Years After Effective Date	Eight Years After Effective Date and Later
Testing costs	$8								
Decisionmaking costs	$18								
Relabeling costs	$73								
Margarine reformulation costs	$302								
Baked products reformulation costs		$32 ($30)	$32 ($28)	$32 ($26)	$32 ($25)	$72 ($52)	$32 ($22)	$72 ($45)	$0
Total costs	$401	$32 ($30)	$32 ($28)	$32 ($26)	$32 ($25)	$72 ($52)	$32 ($22)	$72 ($45)	$0

[1] Costs for Scenario 4 plus 50 percent of the costs of the baked product reformulation.

FDA acknowledges that there is a significant amount of uncertainty in the cost estimates provided here. FDA requests comment on the following uncertainties. The most significant source of potential divergence from the reported estimates would be an ongoing increased cost of substitutes for partially hydrogenated oil for producers of reformulated products. FDA has not included any costs for this item in this analysis, so that, if substitute oils do cost more, the costs here are underestimates.

Reformulation is a second significant area of uncertainty. The unknowns include the number of products that will be reformulated, the cost of reformulation, the number of abandoned attempts at reformulation, the length of time actually needed to reformulate products, and the degree to which the reformulation of some products reduces the cost of reformulating other products. The estimates that are provided in this analysis might be either over- or underestimates of the actual costs of reformulation.

A third major area of uncertainty includes the number of products containing 0.5 g or more *trans* fat per serving and the number of products with affected claims. Actual costs are likely to be higher than those estimated here because this analysis focused only on product groups where a substantial portion of the total number of the products in the group contain partially hydrogenated oil. Among the numerous categories of foods not included in this analysis, a sizable number of additional products may be affected by this proposal.

Finally, restaurants making claims affected by this rule on menus or in other labeling will need either to update the basis for such claims or remove them. FDA does not have information to estimate such costs. However, their existence does suggest that costs reported in this analysis will be lower than the actual costs.

E. Summary of Benefits and Costs

The benefits and costs of the proposed rule occur in different years. In order to compare costs and the ongoing benefits, the agency calculated the present value of benefits and costs for Scenarios 2, 3, and 4 during the compliance period and for 20 years beyond the compliance period. Each scenario assumes that some consumers reduce their consumption of *trans* fat based on labeling changes. Scenario 4 assumes that all margarine products will be reformulated to eliminate *trans* fat. Scenarios 3 and 2 assume in addition progressively more reformulation of baked products as well as assuming that all margarine products will be reformulated to eliminate *trans* fat. Table 25 of this document shows the results.

TABLE 25.—PRESENT VALUE OF BENEFITS AND COSTS OF THE PROPOSED RULE IN MILLIONS (DISCOUNTED TO COMPLIANCE PERIOD AT 7 PERCENT FOR 20 YEARS AFTER THE COMPLIANCE PERIOD)[1]

	Low Estimated Benefits	High Estimated Benefits	Estimated Costs
Scenario 4	$24,893	$50,664	$401
Scenario 3	$26,516	$55,579	$628
Scenario 2	$27,164	$59,190	$854

[1] Based on Tables 5, 6, 22, 23, and 24 of this document.

F. Comparison With Effects of the Rules Implementing the 1990 Amendments

The procedure used to estimate the benefits and costs of the proposed labeling rule differs somewhat from the procedure used to estimate the benefits and costs of the rules implementing the 1990 amendments. The economic analysis of the rules implementing the 1990 amendments did not attempt to estimate the effects of the labeling rules on product reformulation. For this proposed rule, however, FDA has sufficient information to estimate the benefits and costs of product reformulation.

The results of the current benefit-cost analysis, however, could cause some confusion in that the inclusion of reformulation benefits and costs makes the effects of the proposed rule appear large relative to the effects of the rules implementing the 1990 amendments. Although those rules affected far more labels and products, FDA did not estimate the potentially very large effects of reformulation induced by those rules. To allow comparisons between the effects of this proposed rule and the effects of the rules implementing the 1990 amendments, FDA has also estimated only the relabeling effects of this proposed rule. The relabeling costs of the proposed rule, as shown in Tables 22 to 24 would be approximately $100 million during the compliance period. FDA calculated this estimate by assuming that margarine products would be relabeled with their existing formulations rather than being reformulated. The annual direct benefits, which begin 3 years after the effective date for the proposed rule, would be approximately 5 percent of the total after 10 years, or $171 million to $394 million per year.

The present value of the benefits and costs of the rules implementing the 1990 amendments were estimated for 20 years at a 5 percent rate of discount. To make the current rule comparable, FDA estimated the present value of this proposed rule for a 20-year period at a 5 percent rate of discount. Table 26 of this document shows the results of the comparison.

TABLE 26.—COMPARISON OF THE BENEFITS AND COSTS OF THE PROPOSED RULE AND THE BENEFITS AND COSTS OF THE RULES IMPLEMENTING THE 1990 AMENDMENTS (DISCOUNTED AT 5 PERCENT FOR 20 YEARS)

	Benefits	Costs
Rules implementing the 1990 amendments	$4.4 to $26.5 billion	$1.4 to 2.3 billion
This proposed rule	$1.7 to $3.8 billion	$100 million

VII. Initial Regulatory Flexibility Analysis

A. Introduction

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would reduce the economic effect of the rule on small entities.

B. Economic Effects on Small Entities

1. Number and Type of Small Entities Affected

The proposed rule will affect food processors in several different industries. Table 27 of this document shows the number of small businesses likely to be affected in each SIC. FDA calculated the number of businesses from a search using Dun & Bradstreet (Ref. 73). The number of firms listed for each code includes all small firms in the industry category producing products that contain *trans* fat. The SBA size standards apply to the 4-digit SIC codes associated with each product group.

TABLE 27.—NUMBER OF SMALL BUSINESSES AFFECTED (NUMBERS ARE ROUNDED TO THE NEAREST TEN)

Description	Standard Industry Classification and Dun's Market Identifiers Code	Small Business Administration Size Standard (employees)	Number of Small Firms
Frozen Breakfast Foods	20389901, 20389904, 20389910	500	10
Cereal	2043	1,000	60
Baking Mixes	204103	500	40
Breading Products, Frozen Baked Goods, Refrigerated Bread and Pastry, Breads	2051	500	3,000
Crackers Cookies	2052	750	660
Baking Needs, Candy, Gum, and Cough Drops	206499	500	430
Shortenings and Oils, and Refrigerated Spreads	207901, 207902, 207999	750	80
Chip Type Snacks	2096	500	320
Total small businesses			4,600

Table 27 of this document slightly overstates the number of small businesses affected by the proposed rule, because it includes some businesses that would be exempt. The criteria for exemption are: (1) Annual sales of fewer than 100,000 units; (2) no claims or other nutrition information on product labels, labeling, or advertising; (3) fewer than 100 full-time employees; and (4) filing of a notice with the Office of Food Labeling (§ 101.9(j)(18)). FDA has previously estimated that the exemption for all foods would affect about 1.8 percent of FDA-regulated foods by volume (see 58 FR 2927 at 2928, January 6, 1993). FDA assumed that the percentage would be the same for the products affected by this proposed rule. Because FDA did not know how the exemption would be distributed across product groups, FDA estimated the effects of exemptions only for the total costs to small businesses.

2. Costs to Small Entities

Partially hydrogenated oils account for almost all of the *trans* fat in foods covered by the proposed rule; its presence in a product is, therefore, a proxy for the presence of *trans* fat. The proposed rule would cause small businesses whose products contain partially hydrogenated oil to test for the amount of *trans* fat per reference amount. The proposed rule would require a firm to relabel any product that contains 0.5 g or more of *trans* fat per serving, unless the firm chooses to reformulate the product to contain less than 0.5 g of *trans* fat per serving.

FDA calculated the costs to small businesses with the same basic model that was used in section VI.D of this document to estimate the total costs. The basic formula is described there in Figure 1. Although the basic cost formula is the same for large and small firms, the individual components of costs differ for large and small firms. Small firms have lower decisionmaking costs, produce fewer products, and market fewer labels. The reprinting costs per label differ by product group and according to whether or not the principal display panel has to be changed. Reformulation is also less likely for small businesses. FDA assumed that margarine producers would be the only small businesses that would choose to reformulate within 10 years after the effective date for the proposed rule. Although FDA made no quantitative estimates of future reformulation costs for small businesses, it assumed that after reformulation practices for other product groups become standard industry knowledge, small businesses would be able to reformulate at far lower cost than estimated for margarine.

FDA estimated the total costs of the proposed rule to small business by estimating the individual categories of costs and summing them. The first category is testing costs. Small businesses would need to test their products to determine the amounts of *trans* fats. FDA did not have direct estimates of the number of products produced by the small businesses affected by the proposed rule. FDA estimated the number of products produced by small businesses by using a sample from the Enhanced Establishment Database (EED) and assuming that the proportion of all products produced by small businesses was the same as the sample proportion (Ref. 73).

FDA then multiplied the number of products in each category by the percent of products in that category containing partially hydrogenated oil. The result is the estimated number of products of small businesses that would have to be tested for *trans* fat shown in Table 28 of this document.

TABLE 28.—NUMBER OF PRODUCTS OF SMALL BUSINESSES CONTAINING PARTIALLY HYDROGENATED OIL

Product	Number of Products	Percent of Products Containing Partially Hydrogenated Oil	Number of Products Containing Partially Hydrogenated Oil
Frozen Breakfast Foods	470	80	380
Cereal	1,150	40	460
Baking Mixes	1,180	75	890
Breading Products	820	85	700
Frozen Baked Goods	1,330	50	670
Refrigerated Bread and Pastry	1,560	5	80
Breads	26,390	50	13,200
Crackers	1,480	100	1,480
Cookies	5,360	95	5,090
Baking Needs	1,380	65	900
Candy, Gum, and Cough Drops	13,390	40	5,360
Shortenings and Oils	1,100	15	170
Refrigerated Spreads	960	70	670
Chip Type Snacks	8,890	70	6,220
Total			36,270

FDA estimated testing costs to be $200 per product, so the total cost of testing for small businesses would be approximately $7 million (36,270 x $200).

Decisionmaking costs would be borne by those small businesses whose products contain 0.5 g or more *trans* fat per reference amount. Table 29 of this document shows the likely number of small businesses with products containing 0.5 g or more *trans* fat per reference amount; these firms would bear decisionmaking costs because of the proposed rule. FDA estimated the number of small businesses affected by multiplying the number of small businesses in each category (see Table 10 of this document) by the percentage of firms in that category making products with 0.5 g or more *trans* fat per reference amount.

TABLE 29.—NUMBER OF SMALL FIRMS WHOSE PRODUCTS CONTAIN 0.5 GRAM (g) OR MORE *trans* FATS PER REFERENCE AMOUNT

Description	SIC and Dun's Market Identifiers Code	Percent of Small Firms Making Products Containing 0.5 g or More *Trans* Fat	Number of Small Firms Making Products Containing 0.5 g or More *Trans* Fat
Frozen Breakfast Foods	20389901 20389904 20389910	60	10
Cereal	2043	5	0
Baking Mixes	204103	60	20
Breading Products, Frozen Baked Goods, Refrigerated Bread and Pastry, Breads	2051	15	450
Crackers Cookies	2052	100	660
Baking Needs, Candy, Gum, and Cough Drops	206499	15	60
Shortenings and Oils, Refrigerated Spreads	207901 207902 207999	50	40
Potato Chips and Similar Snacks	2096	30	100

TABLE 29.—NUMBER OF SMALL FIRMS WHOSE PRODUCTS CONTAIN 0.5 GRAM (g) OR MORE *trans* FATS PER REFERENCE AMOUNT—Continued

Description	SIC and Dun's Market Identifiers Code	Percent of Small Firms Making Products Containing 0.5 g or More *Trans* Fat	Number of Small Firms Making Products Containing 0.5 g or More *Trans* Fat
Total Small Businesses			1,340

The decisionmaking costs for small businesses are estimated to be approximately $3,500 per firm. Total decisionmaking costs would be approximately $5 million (1,340 x $3,500).

FDA estimated reprinting costs for information panels on a per label (SKU) basis. FDA assumed that the proportion of SKU's from small businesses as a whole equaled the proportion in the EED for each category of foods.

Table 30 of this document shows the cost to small businesses of reprinting information panels.

TABLE 30.—REPRINTING COSTS FOR INFORMATION PANELS

Description	Number of SKU's[1]	Cost per SKU	Cost per Product Group
Frozen Breakfast Foods	230	$1,000	$230,000
Cereal	150	$0	$0
Baking Mixes	670	$300	$201,000
Breading Products	0	$1,300	$0
Frozen Baked Goods	470	$1,300	$611,000
Refrigerated Bread and Pastry	50	$1,300	$65,000
Breads	9,730	$1,300	$12,649,000
Crackers	1,250	$500	$625,000
Cookies	5,330	$500	$2,665,000
Baking Needs	990	$800	$792,000
Candy, Gum, and Cough Drops	4,590	$800	$3,672,000
Shortenings and Oils	170	$100	$17,000
Refrigerated Spreads	450	$100	$45,000
Chips Type Snacks	4,150	$200	$830,000
Total	28,230		$22,402,000

[1] Stockkeeping units.

In addition to the costs of reprinting information panels, small businesses making claims may have to change their principal display panels. The redesign and reprinting cost per SKU change for a small business is estimated to be $1,200. FDA estimated that small businesses accounted for about 50 percent of the labels (SKU's) and about 50 percent of the products that would require changes to the principal display panel. The total number of SKU's estimated in section VI.D.4.a of this document to require such changes was 2,990; small businesses therefore accounted for 1,500 products (0.5 x 2,990). The marketing and administrative costs per product change for a small business is estimated to be $5,500. The total number of products estimated in section VI.D.4.b

of this document to require changes was 2,440; small businesses therefore accounted for 1,220 products (0.5 x 2,440). The total cost to small businesses of changing principal display panels would be $9 million (($1,200 x 1,500) + ($5,500 x 1,220)).

FDA assumed that the only small businesses that would reformulate products to eliminate or reduce *trans* fat would be margarine producers responding to market pressures. The reformulation costs for small businesses producing margarine equals the reformulation costs per product multiplied by the number of products produced by small firms, plus the reformulation costs per SKU times the number of SKU's produced by small firms. FDA assumed that 20 percent of the 670 margarine products to be reformulated, or 134, are produced by small businesses. FDA estimated the cost of formulation and testing to be $440,000 per product. The number of SKU's affected is estimated to be 146 (0.2 x 730). The inventory loss is estimated to be $10,000 per SKU. Table 31 of this document shows the margarine reformulation costs for small businesses.

TABLE 31.—MARGARINE REFORMULATION COSTS FOR SMALL BUSINESSES

	Number	Costs per Product or per SKU[1]	Total Costs for All Products or SKU's
Products	134	$440,000	$59 million
SKU's	146	$10,000	$2 million

[1] Stockkeeping unit.

Table 32 of this document shows the total costs to small businesses of the proposed rule. The adjusted total costs of the proposed rule equal the unadjusted total minus $7 million, 1.8 percent of all compliance period costs of the proposed rule ($401 million x 0.018) (see 58 FR 2927 at 2928, January 6, 1993).

TABLE 32.—TOTAL COSTS FOR SMALL BUSINESSES (IN MILLIONS OF DOLLARS)

Type of Cost	Amount
Testing costs	$7
Decisionmaking costs	$5
Costs of reprinting information panel	$22
Costs changing principal display panel	$9
Formulation and testing costs	$59
Inventory costs	$2
Total	$104
Total adjusted for exemptions	$97

C. Regulatory Options

The Regulatory Flexibility Act requires that FDA consider options for regulatory relief for small entities. Some regulatory relief is already built into the proposed rule. The uniform compliance date should give small entities sufficient time to avoid many potential costs of the rule, such as loss of inventory.

1. Exemption for Small Businesses

The exemption of small businesses from the provisions of the proposed rule would provide regulatory relief. Table 32 of this document shows that small businesses are expected to bear total costs of about $100 million as a result of the proposed rule, an average of $22,600 per small business. As a first approximation, then, exempting small businesses would reduce the burden by an average of $22,600 per small business.

FDA believes that this option would not be desirable. On the one hand, because so many of the businesses in the food processing industry are classified as small by SBA, if small businesses are exempted, much of the potential benefits from the proposed rule would not be realized. On the other hand, exempt businesses may be forced by market pressures to adopt the proposed label in any case. In addition, under section 403(q)(5)(E) of NLEA, very small producers (those with fewer than 100 full-time employees) that: (1) File a notice with the Office of Food Labeling; (2) make very low volume products (fewer than 100,000 units annually); and (3) place no claims or other nutrition information on product labels, labeling, or advertising would already be exempt from this proposed rule.

2. Longer Compliance Period for Small Businesses

Longer compliance periods provide regulatory relief for small businesses. FDA has estimated the costs based on a 2-year compliance period. The estimated costs will decrease if small businesses are given more than two years to comply with the proposed rule.

Labeling costs (decisionmaking, redesign, and printing) fall as the compliance period rises. With the base period of 2 years, labeling costs double with each halving of the length of the compliance period and fall by one-half for each doubling of the compliance period. Testing and reformulation costs also decline with a lengthening of the compliance period. Small businesses would have more opportunity to benefit from technology transfer from large businesses making similar products.

Table 33 of this document shows how the burden on small businesses falls as the compliance period is extended to 18 and 24 months beyond the effective date. The weights used were the proportion of small business costs represented by each component.

TABLE 33.—EFFECT OF COMPLIANCE PERIOD ON SMALL BUSINESS COSTS (ADJUSTMENT FACTORS RELATIVE TO EFFECTIVE DATE)

	At Proposed Effective Date	18 Months After Proposed Effective Date	24 Months After Proposed Effective Date
Decisionmaking costs	100%	75%	50%
Testing costs	100%	97%	93%
Printing costs	100%	75%	50%
Reformulation costs	100%	97%	93%
Weighted average costs	100%	89%	78%

In other words, the costs to small businesses would fall by about 11 percent with an 18-month extension beyond a 2-year compliance period and by about 22 percent with a 24-month extension beyond a 2-year compliance period. FDA will evaluate the length of the compliance period if it finalizes this proposal.

3. Exemptions for Particular Products Produced by Small Entities

In the category of breakfast foods, the average intake of *trans* fat for both men and women is less than one-tenth of a gram per day. Because the entire category contributes so little to the overall dietary intake of *trans* fats, exempting small businesses in this category from the rule would have small effects on health. The exemption, however, would provide regulatory relief for approximately 70 small businesses (including cereal and frozen breakfast foods). The total burden on small businesses would fall by less than $500,000 (the sum of $316,000 relabeling costs and $167,000 testing costs for 835 products). The relief offered by this option, then, would be small.

An objection to this option for regulatory relief is that by exempting an entire class of products, FDA could create incentives for small firms to create products in that category. These new products would have no effective limits on *trans* fat. The exemption would therefore allow small firms to develop products with high *trans* fat content but no indication of that content on the label. The contribution of breakfast cereals to total dietary intake of *trans* fats could increase because of the exemption. The most telling objection to this option is that exempting some products from the proposed labeling rule would make the nutrition facts panel inconsistent across product categories. This inconsistency would be counter to the intent of the 1990 amendments. It would undermine the policy goal of providing consistent nutrition information to consumers.

D. Recordkeeping and Reporting Requirements

The Regulatory Flexibility Act requires FDA to include a description of the recordkeeping and reporting required for compliance with this proposed rule. This proposed rule does not require the preparation of a report or a record.

E. The Burden on a Small Business: A Typical Small Business

The average cost per small business would be about $22,600 ($104 million/4,600 firms). In this section FDA will show how a hypothetical small business could incur this average cost. Although the entity is hypothetical, the cost estimate is based on costs that a single entity could in fact bear as a result of the proposed rule. Suppose that a small business must test and possibly relabel—but does not reformulate—its products. The firm's three products are in the bread category and three of its four labels contain claims. The other product contains less than 0.5 grams of *trans* fat per serving and, therefore, its label need not be changed. Table 34 of this document shows the costs for this hypothetical typical small business. The cost can be compared to some plausible level of sales revenue to estimate the potential burden of the rule.

TABLE 34.—COSTS FOR A HYPOTHETICAL SMALL BUSINESS

Decisionmaking costs	$3,500 per small business	$3,500
Testing costs	$200 per product for 3 products	$600

TABLE 34.—COSTS FOR A HYPOTHETICAL SMALL BUSINESS—Continued

Reprinting information panel costs	$1,300 per SKU[1] for 3 SKU's	$3,900
Changing principal display panels	$1,200 per SKU for 3 SKU's	$3,600
Changing principal display panels costs per product	$5,500 per product for 2 products	$11,000
Total costs		$22,600

[1] Stockkeeping unit.

The median firm in the food groups covered by the proposed rule has annual sales of about $500,000. The proposed rule could therefore lead to a one-time burden of about 5 percent of annual sales ($22,600/$500,000). If the firm borrowed the funds to pay for the label changes and other costs at 7 percent for 10 years, the annual payments would be about $3,200. This estimate may overstate the burden in that the firm may pass most of the cost on to consumers in the form of higher prices for its products. Small margarine producers will bear much higher costs if market pressures force them to reformulate. If the firms are large enough so that they are not exempted from this rule, they will compare potential market share losses with the cost of reformulation. FDA believes that, although the costs of reformulation are large ($450,000 per product), the product volume of even a small plant is large enough to make reformulation the logical choice.

F. Summary

FDA finds that under the Regulatory Flexibility Act (5 U.S.C. 605(b)) this proposed rule will have a significant economic impact on a substantial number of small entities. Approximately 4,600 small businesses could be affected by the rule. The total burden on small entities is estimated to be more than $100 million.

VIII. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses for rules that would cost more than $100 million in 1 single year. The proposed rule qualifies as significant rule under the statute. FDA has carried out the cost-benefit analysis in sections VI.C and VI.D of this document The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on:

A. Future costs;

B. Particular regions, communities, or industrial sectors;

C. National productivity and economic growth;

D. Full employment and job creation; and,

E. Exports.

A. Future Costs

FDA estimated some of the future costs of the proposed rule in section VI.D of this document. The reported costs include costs incurred during the compliance period and up to 7 years after the effective date. Section VI.D of this document also includes some qualitative discussion of costs that would occur beyond that time period. Most of the costs of the rule, however, would occur in the years immediately after the publication of a final rule. Future costs beyond that period would likely be small, because the food industry would have adjusted to the new requirements by that time.

B. Particular Regions, Communities, or Industrial Sectors

The proposed rule applies to the food industry and would, therefore, affect that industry disproportionately. Any long-run increase in the costs of food production would largely be passed on to the entire population of consumers.

C. National Productivity and Economic Growth

The proposed rule is not expected to substantially affect productivity or economic growth. It is possible that productivity and growth in certain sectors of the food industry could be slightly lower than otherwise because of the need to divert research and development resources to compliance activities. The diversion of resources to compliance activities would be temporary. Moreover, FDA anticipates that, because the health benefits are estimated to be large, both productivity and economic growth would be higher than in the absence of the rule. In section VI.C.3 of this document, FDA estimated benefits from the reduction in functional disability

associated with a reduction in nonfatal CHD. A reduction of functional disability would result in an increase in productivity. The increased health of the population and the reduction in direct and indirect health costs could increase both productivity and economic growth.

D. Full Employment and Job Creation

The human resources devoted to producing certain foods would be redirected by the proposed rule. The proposed rule could lead to some short-run unemployment as a result of the structural changes within the food industry, the rise of some product lines and decline of others. The growth of employment (job creation) could also be temporarily slower.

E. Exports

Because the proposed rule does not mandate any changes in products, current export products will not be required to change in any way. Food processors, however, do not necessarily distinguish between production for export and production for the domestic market. The effect of the proposed rule on U.S. food exports depends on how foreign consumers react to information about *trans* fats and to product formulations that contain no partially hydrogenated oils. The new label and possible new formulations could either increase or decrease exports. Germany and certain other European countries, for example, do not currently use partially hydrogenated oils, so the proposed rule could make U.S. exports of margarine and other reformulated products more attractive to consumers in those countries than they have been. However, it could also make U.S. exports of unreformulated products that reveal the presence of *trans* fat less attractive to consumers in those countries than they have been.

IX. Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the next paragraphs below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated information collection techniques or other forms of information technology.

Title: Food Labeling; *Trans* Fatty Acids in Nutrition Labeling and Nutrient Content Claims.

Description: Section 403(q)(1)(A) and (q)(1)(B) of the act requires that the label or labeling of a food bear nutrition information on the amount of nutrients present in the product. Under these provisions of the act and section 2(b) of the 1990 amendments, FDA has issued regulations in § 101.9(c)(2) that require that the nutrition facts panel disclose information on the amounts of fat and certain fatty acids in the food product. Similarly, under the provisions of section 403(q)(5)(F) of the act, FDA has issued regulations in § 101.36(b) that specify the nutrition information that must be on the label or labeling of dietary supplements.

The regulations set forth in this proposed rule would require producers of foods, including dietary supplements, that contain 0.5 g or more of *trans* fatty acids per serving to disclose in the nutrition label the amount of *trans* fatty acids present in such foods. To do so, the proposed

rule would require that the amount and the %DV for saturated fatty acids disclosed in the nutrition label of a food represent the combined amount of saturated and *trans* fatty acids. In addition, the amount of *trans* fatty acids would be disclosed in a footnote.

Section 403(r)(2)(B) of the act requires that the labeling of any food bearing a nutrient content claim that contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related must contain, prominently and in immediate proximity to such nutrient content claim, a disclosure statement specified by the statute. The proposal would also establish the nutrient content claim ''*trans* fat free'' as an authorized nutrient content claim for food, including dietary supplements. Any food bearing a ''*trans* fat free'' nutrient content claim would be required to include a footnote in the nutrition label disclosing that the product contains 0 g *trans* fatty acids. In addition, food products bearing a ''*trans* fat free'' nutrient content claim would be required to disclose the level of total fat and cholesterol, if present at significant levels.

Description of Respondents: Persons and businesses, including small businesses.

TABLE 35.—ESTIMATED REPORTING BURDEN[1]

21 CFR Section	Number of Respondents	Responses per Respondents	Total No. of Responses	Hours per Response	Total hours	Operating costs
101.9(c)(2)(i) and (d)(7)(ii)[2]	1,880		38,670	2	77,340	$38,256,000
101.36(b)(2)[2]	40		300	2	600	$210,000
101.62(c)	25	4	100	0.5	50	$70,000
Totals	1,945		39,070		77,990	$38,536,000

[1] There are no capital cost or maintenance costs associated with this collection of information.
[2] The number of responses per respondent under this section varies greatly depending upon the size of the firm and the numbers and types of products marketed by the firm.

The impact of the proposed requirements concerning *trans* fatty acids would be largely a one-time burden created by the need for firms to revise the labels for those existing products containing *trans* fatty acids. FDA estimated the operating costs for food products that might be affected by this proposed rule by combining the approximate cost of analysis to determine those products containing more than 0.5 g of *trans* fatty acids and the approximate cost of revising the labels for those products conta ining more than 0.5 g of *trans* fatty acids. As noted in section VI of this document in the Preliminary Regulatory Impact Analysis, FDA estimates that the approximate cost of analysis to determine the amount of *trans* fatty acids in affected products to be approximately $8,376,000 for 41,800 products (see Table 8 of this document). Also, as noted in section VI of this document, FDA estimates that there are approximately 1,880 firms producing products that would be affected by this proposed rule. Further, FDA estimates that there are approximately 38,670 SKU's for food products, other than dietary supplements, that would be affected by this proposed rule with the associated operating costs for revising labels of $29,880,000 (see Table 13 of this document).

In the final rule establishing requirements for the nutrition labeling of dietary supplements, FDA estimated that there were approximately 850 suppliers of dietary supplements and that they had on average 40 products each (62 FR 49826 at 49846). Although FDA is uncertain as to exactly how many dietary supplement suppliers (certainly, fewer than 40 suppliers) have products that contain *trans* fatty acids and welcomes comments on this point, based upon its experience, it believes that less than 1 percent of the approximate total of 34,000 dietary supplements, or approximately 300, would contain *trans* fatty acids. Based upon its knowledge of food labeling, FDA estimates that firms would require less than 2 hours per product to comply with the nutrition labeling requirements in § 101.36(b)(2) of a final rule based on this proposal.

FDA also estimates that approximately 25 firms would choose to make *trans* fatty acid free claims under proposed § 101.62(c)(6) on approximately 4 products per firm. Because the regulations supply the wording that would appear on the label, the making of a "*trans* fat free" claim and

the required disclosure of 0 g *trans* fatty acids in an accompanying footnote would impose no burden and would not constitute a ''collection of information'' under the PRA. Rather, the proposed nutrient content claim ''*trans* fat free'' and accompanying footnote would be a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320(c)(2)). Because the information on total fat and cholesterol levels required to be disclosed under § 101.62(c) would be information that the firms would already have, FDA estimates that this additional requirement would add less that 0.5 hours burden for each product.

For the requirements in §§ 101.36(b)(2) and 101.62(c), FDA has estimated operating costs by combining the approximate cost of analysis to determine the level of *trans* fatty acids in the affected products requiring disclosure of *trans* fatty acids ($200 per product) and the approximate cost of revising labels for those products ($500 per product). Thus, FDA tentatively finds that the requirements of a final rule based on this proposal would result in total one-time operating costs of $38,536,000. FDA expects that, with at least a 1-year compliance date, firms will coordinate labeling revisions required by any final rule that may issue based on this proposal with other planned labeling for its products.

In compliance with the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by (*insert date 30 days after date of publication in the* **Federal Register**), to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

XI. Effective Date

The agency proposes that any final rule that may issue based upon this proposal become effective in accordance with the uniform effective date for compliance with food labeling requirements that is announced by notice in the **Federal Register** and that is not sooner than

1 year following publication of any final rule based on this proposal. However, FDA will not object to voluntary compliance immediately upon publication of the final rule.

XII. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the* **Federal Register**), submit to the Dockets Management Branch (address above) written comments regarding this proposal, except that written comments regarding collection of information should be submitted to the Office of Information and Regulatory Affairs, OMB (address above), on or before (*insert date 30 days after date of publication in the* **Federal Register**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

XIII. References

The following references have been placed in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.9 is amended by revising paragraphs (c)(2)(i) and (d)(7)(ii) to read as follows:

§ 101.9 Nutrition labeling of food.

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(c) * * *

(2) * * *

(i) ''Saturated fat,'' or ''Saturated'': A statement of the number of grams of saturated fat in a serving, defined as the sum of the number of grams per serving of all fatty acids containing no double bonds (i.e. ''saturated fatty acids'') plus the number of grams per serving of any unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration (i.e., ''*trans* fatty acids'' or ''*trans* fat'').

(A) The label declaration of saturated fat content information (i.e., the combined value of saturated fatty acids plus *trans* fatty acids) is not required for products that contain less than 0.5

gram of total fat in a serving if no claims are made about fat, fatty acids, or cholesterol content, and if ''calories from saturated fat'' is not declared. Except as provided for in paragraph (f) of this section, if a statement of the saturated fat content is not required and, as a result, not declared, the statement ''Not a significant source of saturated fat'' shall be placed at the bottom of the table of nutrient values. The term ''Saturated fat'' or ''Saturated'' shall be indented and the combined value of saturated fatty acids and *trans* fatty acids expressed as grams per serving to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram of saturated fatty acids and less than 0.5 gram of *trans* fatty acids, the content when declared, shall be expressed as zero.

(B) When 0.5 or more grams per serving of *trans* fatty acids are present, the heading shall be followed by an asterisk (or other symbol) (e.g., ''Saturated fat*'') referring to another asterisk (or other symbol) at the bottom of the nutrition label adjacent to a footnote stating that the product ''Includes ____g *trans* fat,'' with the blank specifying the amount of *trans* fat present in a serving. Optionally, when less than 0.5 gram per serving of *trans* fatty acids are present, manufacturers may, but need not, use an asterisk (or another symbol) following ''Saturated fat'' to refer to the footnote ''Includes (or contains) 0 g *trans* fat'' or ''Includes (or contains) no *trans* fat,'' except that the footnote is required when a fatty acid or cholesterol claim is made. The term ''*trans* fatty acids'' may be used interchangeably with ''*trans* fat.'' Amounts specified within the footnote shall be expressed as grams per serving to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams.

* * * * *

(d) * * *

(7) * * *

(ii) A listing of the percent of the DRV as established in paragraphs (c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading ''% Daily Value'' established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for

each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The percent shall be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. When *trans* fatty acids are present in a food, the percent declared for saturated fat shall be calculated by dividing the amount declared on the label for saturated fat, which includes *trans* fatty acids, by the DRV for saturated fat. The numerical value shall be followed by the symbol for percent (i.e., %).

* * * * *

3. Section 101.13 is amended by revising paragraphs (h)(1), (h)(2), and (h)(3) to read as follows:

§ 101.13 Nutrient content claims—general principles.

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(h) * * *

(1) If a food, except a meal product as defined in § 101.13(l), a main dish product as defined in § 101.13(m), or food intended specifically for use by infants and children less than 2 years of age, contains more than 13.0 g of fat, 4.0 g of saturated fat and *trans* fat combined, 60 milligrams (mg) of cholesterol, or 480 mg of sodium per reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the ''as prepared'' form), then that food must bear a statement disclosing that the nutrient exceeding the specified level is present in the food as follows: ''See nutrition information for ————

content'' with the blank filled in with the identity of the nutrient exceeding the specified level, e.g., ''See nutrition information for fat content.''

(2) If a food is a meal product as defined in § 101.13(l), and contains more than 26 g of fat, 8.0 g of saturated fat and *trans* fat combined, 120 mg of cholesterol, or 960 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

(3) If a food is a main dish product as defined in § 101.13(m), and contains more than 19.5 g of fat, 6.0 g of saturated fat and *trans* fat combined, 90 mg of cholesterol, or 720 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

* * * * *

4. Section 101.14 is amended by revising paragraph (a)(5) to read as follows:

§ 101.14 Health claims: general requirements.

(a) * * *

(5) *Disqualifying nutrient levels* means the levels of total fat, saturated fat and *trans* fat combined, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. These levels are 13.0 grams (g) of fat, 4.0 g of saturated fat and *trans* fat combined, 60 milligrams (mg) of cholesterol, or 480 mg of sodium, per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g. For dehydrated foods that must have water added to them prior to typical consumption, the per 50 g criterion refers to the as prepared form. Any one of the levels, on a per reference amount customarily consumed, a per labeled serving size or, when applicable, a per 50 g basis, will disqualify a food from making a health claim unless an exception is provided in subpart E of this part, except that:

(i) The levels for a meal product as defined in § 101.13(l) are 26.0 g fat, 8.0 g of saturated fat and *trans* fat combined, 120 mg of cholesterol, or 960 mg of sodium per labeled serving size, and

(ii) The levels for a main dish product as defined in § 101.13(m) are 19.5 g of fat, 6.0 g of saturated fat and *trans* fat combined, 90 mg of cholesterol, or 720 mg of sodium per labeled serving size.

* * * * *

5. Section 101.36 is amended by adding a sentence after the first sentence in paragraph (b)(2)(i) and by revising paragraph (b)(2)(iii) introductory text to read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

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(b) * * *

(2) * * *

(i) * * * When *trans* fatty acids are present, they shall be declared in accordance with § 101.9(c)(2)(i). * * *

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(iii) The percent of the Daily Value of all dietary ingredients declared under paragraph (b)(2)(i) of this section shall be listed, except that the percent for protein may be omitted as provided in § 101.9(c)(7) and when *trans* fatty acids are present in a food, the percent for saturated fat shall be calculated by dividing the amount declared on the label for saturated fat, which includes *trans* fatty acids, by the DRV for saturated fat; no percent shall be given for subcomponents for which DRV's have not been established (e.g., sugars); and, for labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women, no percent shall be given for total fat, saturated

fat, cholesterol, total carbohydrate, dietary fiber, vitamin K, selenium, manganese, chromium, molybdenum, chloride, sodium, or potassium.

* * * * *

6. Section 101.62 is amended by adding paragraph (c)(6), by revising paragraph (c) introductory text, and paragraphs (c)(2)(i), (c)(3)(i), (c)(4)(i), (c)(5)(i), (d)(1)(i)(C), (d)(1)(ii)(C), (d)(2)(i)(B), (d)(2)(ii)(B), (d)(2)(iii)(B), (d)(2)(iv)(B), (d)(3), (d)(4)(i)(B), (d)(4)(ii)(B), (d)(5)(i)(B), (d)(5)(ii)(B), and (e) to read as follows:

§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

* * * * *

(c) ''*Fatty acid content claims.*'' The label or labeling of foods that bear claims with respect to the level of saturated fat or *trans* fat shall disclose the level of total fat and cholesterol in the food in immediate proximity to such claim each time the claim is made and in type that shall be no less than one-half the size of the type used for the claim with respect to the level of saturated fat or *trans* fat. Declaration of cholesterol content may be omitted when the food contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed or in the case of a meal or main dish product less than 2 mg of cholesterol per labeled serving. Declaration of total fat may be omitted with the terms defined in paragraphs (c)(1) and (c)(6) of this section when the food contains less than 0.5 g of total fat per reference amount customarily consumed or, in the case of a meal product or a main dish product, when the product contains less than 0.5 g of total fat per labeled serving. The declaration of total fat may be omitted with the terms defined in paragraphs (c)(2) through (c)(5) of this section when the food contains 3 g or less of total fat per reference amount customarily consumed or in the case of a meal product or a main dish product, when the product contains 3 g or less of total fat per 100 g and not more than 30 percent calories from fat.

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(2) * * *

(i) The food contains 1 g or less of saturated fat and less than 0.5 g of *trans* fat per reference amount customarily consumed and not more than 15 percent of calories from saturated fat and *trans* fat combined; and

* * * * *

(3) * * *

(i) The product contains 1 g or less of saturated fat and less than 0.5 g of *trans* fat per 100 g and less than 10 percent of calories from saturated fat and *trans* fat combined; and

* * * * *

(4) * * *

(i) The food contains at least 25 percent less saturated fat and at least 25 percent less saturated fat and *trans* fat combined per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

* * * * *

(5) * * *

(i) The food contains at least 25 percent less saturated fat and at least 25 percent less saturated fat and *trans* fat combined per 100 g of food than an appropriate reference food as described in § 101.13(j)(1); and

* * * * *

(6) The terms ''*trans* fat free,'' ''free of *trans* fat,'' ''no *trans* fat,'' ''zero *trans* fat,'' ''without *trans* fat,'' ''trivial source of *trans* fat,'' ''negligible source of *trans* fat,'' or ''dietarily insignificant source of *trans* fat'' (with ''*trans* fatty acids'' allowable as a synonym for ''*trans* fat'') may be used on the label or in the labeling of foods, provided that:

(i) The food contains less than 0.5 g of *trans* fat and less than 0.5 g of saturated fat per reference amount customarily consumed and per labeled serving or, in the case of a meal product

or a main dish product, less than 0.5 g of *trans* fat and less than 0.5 g of saturated fat per labeled serving; and

(ii) The food contains no ingredient that is generally understood by consumers to contain *trans* fat unless the listing of the ingredient in the ingredient statement is followed by an asterisk (or other symbol) that refers to the statement below the list of ingredients which states, ''adds a trivial amount of *trans* fat,'' ''adds a negligible amount of *trans* fat,'' or ''adds a dietarily insignificant amount of *trans* fat; and

(iii) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower *trans* fat content, it is labeled to disclose that *trans* fat is not usually present in the food (e.g., ''Corn oil, a*trans* fat free food'').

(d) * * *

(1) * * *

(i) * * *

(C) The food contains 2 g or less of saturated fat and *trans* fat combined per reference amount customarily consumed or, in the case of a meal product or main dish product, 2 g or less of saturated fat and *trans* fat combined per labeled serving; and

* * * * * *

(ii) * * *

(C) The food contains 2 g or less of saturated fat and *trans* fat combined per reference amount customarily consumed or, in the case of a meal product or main dish product, 2 g or less of saturated fat and *trans* fat combined per labeled serving; and

* * * * * *

(2) * * *

(i) * * *

(B) The food contains 2 g or less of saturated fat and *trans* fat combined per reference amount customarily consumed; and

* * * * *

(ii) * * *

(B) The food contains 2 g or less of saturated fat and *trans* fat combined per reference amount customarily consumed; and

* * * * *

(iii) * * *

(B) The food contains 2 g or less of saturated fat and *trans* fat combined per reference amount customarily consumed;

* * * * *

(iv) * * *

(B) The food contains 2 g or less of saturated fat and *trans* fat combined per reference amount customarily consumed;

* * * * *

(3) The terms defined in paragraph (d)(2) of this section may be used on the label and in labeling of meal products as defined in § 101.13(l) or a main dish product as defined in § 101.13(m) provided that the product meets the requirements of paragraph (d)(2) of this section except that the determination as to whether paragraph (d)(2)(i) or (d)(2)(iii) of this section applies to the product will be made only on the basis of whether the meal product contains 26 g or less of total fat per labeled serving or the main dish product contains 19.5 g or less of total fat per labeled serving; the requirement in paragraphs (d)(2)(i)(A) and (d)(2)(iii)(A) of this section shall be limited to 20 mg of cholesterol per 100 g, and the requirement in paragraphs (d)(2)(i)(B) and (d)(2)(iii)(B) of this section shall be modified to require that the food contain 2 g or less of saturated fat and *trans* fat combined per 100 g rather than per reference amount customarily consumed.

(4) * * *

(i) * * *

(B) The food contains 2 g or less of saturated fat and *trans* fat combined per reference amount customarily consumed; and

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(ii) * * *

(B) The food contains 2 g or less of saturated fat and *trans* fat combined per reference amount customarily consumed;

* * * * *

(5) * * *

(i) * * *

(B) The food contains 2 g or less of saturated fat and *trans* fat combined per 100 g; and

* * * * *

(ii) * * *

(B) The food contains 2 g or less of saturated fat and *trans* fat combined per 100 g;

* * * * *

(e) ''*Lean*'' and ''*extra lean*'' claims. (1) The term ''lean'' may be used on the label or in labeling of foods except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food is a seafood or game meat product and as packaged contains less than 10 g of total fat, 4.5 g or less of saturated fat and*trans* fat combined, and less than 95 mg of cholesterol per reference amount customarily consumed and per 100 g;

(2) The term defined in paragraph (e)(1) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food contains less than 10 g of total fat, 4.5 g or less of saturated fat and *trans* fat combined, and less than 95 mg of cholesterol per 100 g and per labeled serving;

(3) The term ''extra lean'' may be used on the label or in labeling of foods except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that

the food is a discrete seafood or game meat product and as packaged contains less than 5 g of total fat, less than 2 g of saturated fat and *trans* fat combined, and less than 95 mg of cholesterol per reference amount customarily consumed and per 100 g; and

(4) The term defined in paragraph (e)(3) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food contains less than 5 g of total fat, less than 2 g of saturated fat and *trans* fat combined, and less than 95 mg of cholesterol per 100 g and per labeled serving.

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JUL 29 1999

Dated: _____

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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NOTE: The following Appendix A and Appendix B will not appear in the Code of Federal Regulations

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